

US3312395 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:01:36

All time stamps listed in this document are displayed in GMT

US3312395

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

Participant ID

US3312395

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

US3312395

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3312395

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input 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

US3312395

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 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 type="radio"/>
	Amendment 3 <input checked="" 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

US3312395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312395

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Were any significant conditions reported?

Yes ☒
No ☐

US3312395

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	HEPATITIS C VIRUS
Start date (dd MMM yyyy)	UN UNK 1984
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3312395

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

US3312395

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3312395

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	FASCIOTOMY RIGHT LEG (LEFT LEG DONOR SITE)
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3312395

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	GUNSHOT WOUND RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3312395

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3312395

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	NEUROLEPTIC PARKINSONISM
Start date (dd MMM yyyy)	UN JAN 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3312395

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312395

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:50 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:50
Height (<i>xxx.x</i>)	69.5 in
Weight (<i>xxx.x</i>)	189 lb
BMI (<i>xxx.x</i>)	27.56780 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" 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)	

US3312395

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3312395

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3312395

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

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	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3312395

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110207

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 ☒

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Height	ND - Not Done
Weight	ND - Not Done

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:50
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

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)	31 AUG 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:29
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

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.

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 11:58

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

US3312395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	11:21 (24 HR)
Collection date and time (derived)	31 AUG 2020 11:21

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:11	31 AUG 2020 11:11
Nasopharyngeal Swab 2	No		

US3312395

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:03

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:31

PC Open Date & Time

31 AUG 2020 12:18

PC Close Date & Time

31 AUG 2020 14:48

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:14

PC Open Date & Time

31 AUG 2020 15:43

PC Close Date & Time

01 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 18:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:18

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 18:24

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

97.5 °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

04 SEP 2020 18:33

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

05 SEP 2020 18:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

31 AUG 2020 12:32

PC Open Date & Time

31 AUG 2020 12:18

PC Close Date & Time

31 AUG 2020 14:48

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:15

PC Open Date & Time

31 AUG 2020 15:43

PC Close Date & Time

01 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

01 SEP 2020 18:09

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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 ☒

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

02 SEP 2020 19:19

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

03 SEP 2020 18:25

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

04 SEP 2020 18:33

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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 ☒

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

05 SEP 2020 18:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

06 SEP 2020 17:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:33
PC Open Date & Time	31 AUG 2020 12:18
PC Close Date & Time	31 AUG 2020 14:48

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 18:15
PC Open Date & Time	31 AUG 2020 15:43
PC Close Date & Time	01 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

51 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

53 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 10:40
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

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 ☒

PRODUCTION RELEASE (v12.003

55 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 18:26
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

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)

57 of 2206

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

59 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:20
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

61 of 2206

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3312395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:08
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

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)	28 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:44
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:45:04

Generated On: 09 Jun 2021 17:01:36

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:13

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

US3312395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:45:04

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	10:37 (24 HR)
Collection date and time (derived)	28 SEP 2020 10:37

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:45:04

Generated On: 09 Jun 2021 17:01:36

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:29	28 SEP 2020 10:29
Nasopharyngeal Swab 2	No		

US3312395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:04

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 11:46

PC Open Date & Time

28 SEP 2020 11:33

PC Close Date & Time

28 SEP 2020 14:03

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	28 SEP 2020 15:13
PC Open Date & Time	28 SEP 2020 14:58
PC Close Date & Time	29 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 17:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 16:05

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 02 OCT 2020 16:33

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

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.

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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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 11:39

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

28 SEP 2020 11:46

PC Open Date & Time

28 SEP 2020 11:33

PC Close Date & Time

28 SEP 2020 14:03

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 15:13

PC Open Date & Time

28 SEP 2020 14:58

PC Close Date & Time

29 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

29 SEP 2020 17:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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 ☒

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

30 SEP 2020 18:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

01 OCT 2020 16:05

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

02 OCT 2020 16:33

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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 ☒

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

03 OCT 2020 19:38

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

05 OCT 2020 11:39

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 11:46
PC Open Date & Time	28 SEP 2020 11:33
PC Close Date & Time	28 SEP 2020 14:03

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 15:15
PC Open Date & Time	28 SEP 2020 14:58
PC Close Date & Time	29 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

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 ☒

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 17:09
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

99 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

101 of 2206

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 16:06
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

103 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 16:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

105 of 2206

EAB) (1725)

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:38
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

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 ☒

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 11:39
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3312395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

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

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:02

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 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

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

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.

US3312395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

10:09 (24 HR)

Collection date and time (derived)

26 OCT 2020 10:09

US3312395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:45:07

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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	01 NOV 2020 09:08:54
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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	09 NOV 2020 17:29:07
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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 NOV 2020 09:10:10
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 08:23:55

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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	02 DEC 2020 08:37:42
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

09 DEC 2020 08:07:58

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

16 DEC 2020 07:24:01

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:32:04

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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	02 JAN 2021 13:11:10
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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	06 JAN 2021 08:07:31
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 08:06:02

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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	21 JAN 2021 08:36:59
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 19:31:32

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

17 FEB 2021 16:56:00

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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	24 FEB 2021 14:34:17
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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 MAR 2021 09:55:52
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 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	17 MAR 2021 18:05:16
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 15:50:56

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

03 APR 2021 08:29:19

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

08 APR 2021 08:05:42

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

14 APR 2021 22:13:10

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

21 APR 2021 18:42:20

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

28 APR 2021 11:38:00

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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="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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 327

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

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

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

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

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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="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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 348

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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="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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 432

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 439

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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="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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 614

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 642

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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="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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 <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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3312395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:01:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		10 MAR 2021 09:56:28

US3312395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:03:51

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:03:51

Generated On: 09 Jun 2021 17:01:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 11:04
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:03:51

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3312395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:03:51

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	30 MAR 2021
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Collection time (00:00-23:59)	12:41 (24 HR)
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Collection date and time (derived)	30 MAR 2021 12:41
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US3312395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:09

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312395

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:36

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"/>

US3312395

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:01:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312395

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	03 MAR 2021
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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
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US3312395

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Date of updated informed consent (<i>dd MMM yyyy</i>)	03 MAR 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>)	03 MAR 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312395

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3312395

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	03 MAR 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 10:10
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	03 MAR 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 11:02
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

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

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3312395

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

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 03 MAR 2021

What was the treatment time? (00:00-23:59) 10:31 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 10:31

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

US3312395

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	09:24 (24 HR)
Collection date and time (derived)	03 MAR 2021 09:24

US3312395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 MAR 2021

Collection time (00:00 - 23:59)

09:23

Collection Date and Time (derived)

03 MAR 2021 09:23

US3312395

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

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3312395

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

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)	30 MAR 2021
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 11:04
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

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)	30 MAR 2021
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 12:29
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3312395

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3312395

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 30 MAR 2021

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 30 MAR 2021 11:58

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

US3312395

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:22:23

Generated On: 09 Jun 2021 17:01:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:22:23

Generated On: 09 Jun 2021 17:01:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312395

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 APR 2021
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 12:24
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312395

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 APR 2021

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

US3312395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 APR 2021
Collection time (00:00-23:59)	12:52 (24 HR)
Collection date and time (derived)	27 APR 2021 12:52

US3312395

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:59:35

Generated On: 09 Jun 2021 17:01:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

AEID	
Adverse event	CERVICALGIA
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)	12 SEP 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)

354 of 2206

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

AEID	USA-US300-2021-MRNA-1273-P30 1000016
Adverse event	MANIC EPISODE
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 FEB 2021
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)	15 FEB 2021
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 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	15 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2206

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

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	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	

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

55 YEAR OLD MAN WHO ON
01FEB2021 WHILE AT SITE FOR
UNBLINDING VISIT, EXHIBITED
STRANGE BEHAVIOR SUCH AS
SPEAKING IN LOUD
NONSENSICAL OUTBURSTS TO
STRANGERS WHILE STANDING
IN HALLWAY. SUBJECT'S
ROOMMATE WHO IS ALSO
SUBJECT'S EMERGENCY
CONTACT WAS PRESENT AND
REPORTED THAT SUBJECT HAS
HISTORY OF SIMILAR
BEHAVIOR IN PAST DUE TO
BIPOLAR DISORDER (NOT
REVEALED AT SCREENING)
WHEN NON-COMPLIANT WITH
MEDICATION. SUBJECT AND
ROOMMATE WERE ADVISED
THAT SUBJECT COULD NOT BE
DOSED WHEN UNSTABLE AND
ROOMMATE AGREED TO TAKE
SUBJECT TO ER OR TO
SUBJECT'S PROVIDER FOR
EVALUATION AND
RE-INITIATION OF THERAPY.
SUBJECT AND ROOMMATE
CALLED TODAY, 17FEB2021 TO
REPORT THAT SUBJECT WAS
HOSPITALIZED FROM
APPROXIMATELY 02FEB2021
THROUGH 15FEB2021 FOR
BIPOLAR EPISODE WITH
PSYCHOTIC FEATURES BUT
THAT HE IS STABLE NOW. MED

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

RECORDS WILL BE PROCURED
AND REVIEWED AND CONTACT
OR VISIT WITH SUBJECT WILL
BE PLANNED TO DECIDE HOW
TO PROCEED IN STUDY.
UPDATE 03/05/21:MED RECORDS
REVIEWED CONFIRMING
SUBJECT'S PAST HISTORY OF
BIPOLAR DISORDER AND
CURRENT EPISODE OF MANIA
DUE TO MEDICATION
NON-COMPLIANCE AND
RECENT SOCIAL STRESSORS.
SUBJECT ALSO HAS HISTORY
OF NEUROLEPTIC
PARKINSONISM POSSIBLY
COMPLICATING THE
COMPLIANCE ISSUE. SUBJECT
WAS ADMITTED FROM 02FEB
THRU 15FEB AND TREATED
WITH DEPAKOTE,
OLANZAPINE, AND ZOLPIDEM
SHOWING STEADY
IMPROVEMENT THROUGH
DISCHARGE. SUBJECT WAS
SEEN AT SITE 03MAR; HE WAS
STABLE AND WAS DOSED
WITHOUT COMPLICATIONS.
MED HX AND CM UPDATED,
SAE CLOSED PER PI

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

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

AEID

Adverse event

NASAL CONGESTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

360 of 2206

EAB) (1725)

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 02:03:06

Generated On: 09 Jun 2021 17:01:36

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 _____	
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)	_____

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

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

Yes ☒

No ☐

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

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	05 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 250

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)

365 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	05 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 60

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)

367 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

371 of 2206

EAB) (1725)

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 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"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 16

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)

373 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 SEP 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"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 12

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)

375 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 SEP 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"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 8

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 18 SEP 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"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication METHYLPREDISOLONE

Prophylaxis Yes ☐
No ☒

Indication CERVICALGIA

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

379 of 2206

EAB) (1725)

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 19 SEP 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"/>

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication DEPAKOTE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR/MANIC EPISODE

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	20 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication ZYPREXA

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR/MANIC EPISODE

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	20 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

Name of Medication ZOLIPIDEM

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR/MANIC EPISODE

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

HS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2206

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 15:36:57

Generated On: 09 Jun 2021 17:01:36

	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)		02 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)		20 APR 2021
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"/>

US3312395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3312395

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:36

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

US3312395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:01:36

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 ☐

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

SAEID	USA-US300-2021-MRNA-1273-P301000016
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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

SAEID	USA-US300-2021-MRNA-1273-P301000016
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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/FEB/2021 12:55
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

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

SAEID	USA-US300-2021-MRNA-1273-P301000016
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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 02:03:08

Generated On: 09 Jun 2021 17:01:36

SAEID	USA-US300-2021-MRNA-1273-P301000016
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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/MAR/2021 08:57
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

US3312395 (Prod: Johnson County Clin-Trials)

US3312395

Form: Participant Creation

Generated On: 09 Jun 2021 17:01:36

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'US3312395'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 15:35:34

US3312395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:53:30
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:01:27

US3312395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:53:30
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 15:35:36

US3312395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:53:30
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:01:27

US3312395

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'SCRN'	System	31 Aug 2020 17:01:27

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 15:35:37

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '55'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'YEARS'	System	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '55'	System	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered 'Male (M)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered 'I'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:07
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:44:57

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered '31 Aug 2020'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Aug 2020'	System	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2020'	System	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered empty.	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered empty.	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:05

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 15:35:36

US3312395

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'I'	System	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:01:36

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:54:36
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:01:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:56:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered 'Yes (Y)'	(b) (4)	11 Sep 2020 22:41:24
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:40:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:40:50
Data point term sent to Coder	System	11 Sep 2020 22:41:57
User entered 'HEPATITIS C VIRUS'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 1984'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2016'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1984'	System	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1984'	System	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2016'	System	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2016'	System	11 Sep 2020 22:41:48

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:43:46
Data point term sent to Coder	System	11 Sep 2020 22:42:57
User entered 'OSTEOARTHRITIS'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 1989'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Sep 2020 22:42:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:11
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Sep 2020 22:42:03
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1989'	System	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1989'	System	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	11 Sep 2020 22:42:03

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Pneumonia staphylococcal, LLT: Methicillin-resistant Staphylococcus aureus pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:43:45
Data point term sent to Coder	System	11 Sep 2020 22:42:58
User entered 'Methicillin-resistant Staphylococcus aureus'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2015'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2015'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2015'	System	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2015'	System	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2015'	System	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2015'	System	11 Sep 2020 22:42:57

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Fascial and bursal therapeutic procedures, PT: Fasciotomy, LLT: Fasciotomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:53:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:53:48
Data point term sent to Coder	System	11 Sep 2020 22:44:00
User entered 'FASCIOTOMY RIGHT LEG (LEFT LEG DONOR SITE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2010'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2010'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2010'	System	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2010'	System	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2010'	System	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2010'	System	11 Sep 2020 22:43:32

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:42:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 05:42:50
Data point term sent to Coder	System	11 Sep 2020 22:44:01
User entered 'GUNSHOT WOUND RIGHT LEG'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'UN UNK 2010'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:15:26
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated per source ' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:20:48
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:20:40
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 03:50:20
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered 'un UNK 2010' reason for change:	Karol Moore (b) (4)	18 Oct 2020 00:20:40
Data Entry Error	(b) (4)	
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:31
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2010'	System	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2010'	System	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2010'	System	18 Oct 2020 00:20:40
User entered empty.	System	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2010'	System	18 Oct 2020 00:20:40
User entered empty.	System	11 Sep 2020 22:43:48

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
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.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 16:37:04
Data point term sent to Coder	(b) (4)	
User entered 'bipolar disorder'	System	06 Mar 2021 16:36:18
	(b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1990'	System	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1990'	System	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:35:56

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 16:38:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 16:38:04
Data point term sent to Coder	System	06 Mar 2021 16:37:18
User entered 'attention deficit hyperactivity disorder'	(b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1990'	System	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1990'	System	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:36:22

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Parkinson's disease and parkinsonism, PT: Parkinsonism, LLT: Drug-induced parkinsonism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Mar 2021 11:19:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:19:49
Data point term sent to Coder	System	06 Mar 2021 16:37:18
User entered 'neuroleptic parkinsonism'	(b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'un Jan 2020'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 2020'	System	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '2020'	System	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:37:02

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Mar 2021 16:48:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 16:48:03
Data point term sent to Coder	System	06 Mar 2021 16:47:25
User entered 'allergy to morphine'	(b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1990'	System	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1990'	System	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:47:17

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 16:49:03
Data point term sent to Coder	(b) (4)	
User entered 'allergy to oxycontin'	Coder Import (b) (4)	06 Mar 2021 16:49:03
	(b) (4)	
	System	06 Mar 2021 16:48:26
	(b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:00:07
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'Jan 1990'	System	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '1990'	System	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:36

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	06 Mar 2021 16:47:34

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered '10:50'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 10:50'	System	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered '69.5' in	Karol Moore (b) (4)	11 Sep 2020 22:44:30
DataPoint set to visible.	(b) (4) System	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered '189' lb	Karol Moore (b) (4)	11 Sep 2020 22:44:30
DataPoint set to visible.	(b) (4) System	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '27.56780'	System	11 Sep 2020 22:44:30
DataPoint set to visible.	System	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'kg/m2'	System	11 Sep 2020 22:44:30
DataPoint set to visible.	System	31 Aug 2020 17:02:12

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'bpm'	System	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'breaths/min'	System	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:15
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:44:30

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53

US3312395

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53

US3312395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:42

US3312395

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:15
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:44:42

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:32
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:45:47

US3312395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:03
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:36

US3312395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:03
User entered '31 Aug 2020'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:36

US3312395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:03
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:36

US3312395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'VISIT1'	System	31 Aug 2020 17:02:36

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 16:34:51

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered '110207'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 16:34:51

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 16:34:51

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:47

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

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)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:47

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:47

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:47

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:02:47

US3312395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:36

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:01:26
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	30 Oct 2020 18:34:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:43:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:43:36

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '10:50'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 10:50'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '97.8' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '65'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'bpm'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '14'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'breaths/min'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '122'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '66'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '12:29'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 12:29'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '59'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'bpm'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '14'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'breaths/min'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '115'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:06:58
User entered '82'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'mmHg'	System	11 Sep 2020 22:47:00

US3312395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:17
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:10

US3312395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:09:17
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:10

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered empty.	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered empty.	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered '31 Aug 2020'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered '11:58'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 11:58'	System	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:23
User entered 'ONCE'	System	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 17:03:07

US3312395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:28

US3312395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:57
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:28

US3312395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:57
User entered '11:21'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:28

US3312395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 11:21'	System	11 Sep 2020 22:47:28

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:10
User entered '31 Aug 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:10
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:10
User entered '11:11'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered '31 Aug 2020 11:11'	System	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:10
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:10
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered empty.	System	11 Sep 2020 22:47:44

US3312395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:12:18
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:47:51

US3312395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'I'	System	11 Sep 2020 22:47:51

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:30:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10db8d12-b3d4-4255-ae98-4475bafb78ee' User entered 'Yes (Y)'	System	31 Aug 2020 17:33:59
	System	31 Aug 2020 17:33:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:31:16', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10db8d12-b3d4-4255-ae98-4475bafb78ee' User entered '98.7'	System	31 Aug 2020 17:33:59
	System	31 Aug 2020 17:33:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:31:23', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10db8d12-b3d4-4255-ae98-4475bafb78ee' User entered 'No (N)'	System	31 Aug 2020 17:33:59
	System	31 Aug 2020 17:33:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:31:53', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10db8d12-b3d4-4255-ae98-4475bafb78ee' User entered '31 Aug 2020 12:31'	System	31 Aug 2020 17:33:59
	System	31 Aug 2020 17:33:59

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 12:18'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 14:48'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:13:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'ee84a1b1-daeb-4328-879f-6c9a921b9f4e' User entered 'Yes (Y)'	System	31 Aug 2020 23:14:16
	System	31 Aug 2020 23:14:16

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:13:45', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'ee84a1b1-daeb-4328-879f-6c9a921b9f4e' User entered '97.8'	System	31 Aug 2020 23:14:16
	System	31 Aug 2020 23:14:16

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:13:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'ee84a1b1-daeb-4328-879f-6c9a921b9f4e'	System	31 Aug 2020 23:14:16
User entered 'No (N)'	System	31 Aug 2020 23:14:16

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:14:14', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'ee84a1b1-daeb-4328-879f-6c9a921b9f4e'	System	31 Aug 2020 23:14:16
User entered '31 Aug 2020 18:14'	System	31 Aug 2020 23:14:16

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 15:43'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 2'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:11', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'af738925-3bd7-4584-8a5a-be8466567a73'	System	01 Sep 2020 23:08:34
User entered 'Yes (Y)'	System	01 Sep 2020 23:08:34

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'af738925-3bd7-4584-8a5a-be8466567a73' User entered '98.7'	System	01 Sep 2020 23:08:34
	System	01 Sep 2020 23:08:34

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:26', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'af738925-3bd7-4584-8a5a-be8466567a73'	System	01 Sep 2020 23:08:34
User entered 'No (N)'	System	01 Sep 2020 23:08:34

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'af738925-3bd7-4584-8a5a-be8466567a73'	System	01 Sep 2020 23:08:34
User entered '01 Sep 2020 18:08'	System	01 Sep 2020 23:08:34

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 3'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:18:17', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67f6810a-1a9f-4ee7-b106-33b415ddc583' User entered 'Yes (Y)'	System	03 Sep 2020 00:18:55
	System	03 Sep 2020 00:18:55

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:18:39', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67f6810a-1a9f-4ee7-b106-33b415ddc583' User entered '97.7'	System	03 Sep 2020 00:18:55
	System	03 Sep 2020 00:18:55

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:18:46', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67f6810a-1a9f-4ee7-b106-33b415ddc583'	System	03 Sep 2020 00:18:55
User entered 'No (N)'	System	03 Sep 2020 00:18:55

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:18:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67f6810a-1a9f-4ee7-b106-33b415ddc583'	System	03 Sep 2020 00:18:55
User entered '02 Sep 2020 19:18'	System	03 Sep 2020 00:18:55

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 4'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7f9734c0-7ba6-4e20-9a80-5ab403853295' User entered 'Yes (Y)'	System	03 Sep 2020 23:24:26
	System	03 Sep 2020 23:24:26

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:14', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7f9734c0-7ba6-4e20-9a80-5ab403853295' User entered '97.6'	System	03 Sep 2020 23:24:26
	System	03 Sep 2020 23:24:26

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:18', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7f9734c0-7ba6-4e20-9a80-5ab403853295'	System	03 Sep 2020 23:24:26
User entered 'No (N)'	System	03 Sep 2020 23:24:26

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7f9734c0-7ba6-4e20-9a80-5ab403853295' User entered '03 Sep 2020 18:24'	System	03 Sep 2020 23:24:26
	System	03 Sep 2020 23:24:26

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 5'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:32:48', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67b425ea-b977-42ca-8543-ac383bfc2b7b' User entered 'Yes (Y)'	System	04 Sep 2020 23:33:08
	System	04 Sep 2020 23:33:08

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:32:57', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67b425ea-b977-42ca-8543-ac383bfc2b7b' User entered '97.5'	System	04 Sep 2020 23:33:08
	System	04 Sep 2020 23:33:08

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67b425ea-b977-42ca-8543-ac383bfc2b7b' User entered 'No (N)'	System	04 Sep 2020 23:33:08
	System	04 Sep 2020 23:33:08

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:04', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '67b425ea-b977-42ca-8543-ac383bfc2b7b' User entered '04 Sep 2020 18:33'	System	04 Sep 2020 23:33:08
	System	04 Sep 2020 23:33:08

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 6'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:20', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '2a53bbfc-34c4-4dba-ad1c-c729391fd0ce' User entered 'Yes (Y)'	System	05 Sep 2020 23:19:28
	System	05 Sep 2020 23:19:28

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '2a53bbfc-34c4-4dba-ad1c-c729391fd0ce' User entered '98.5'	System	05 Sep 2020 23:19:28
	System	05 Sep 2020 23:19:28

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '2a53bbfc-34c4-4dba-ad1c-c729391fd0ce'	System	05 Sep 2020 23:19:28
User entered 'No (N)'	System	05 Sep 2020 23:19:28

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:25', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '2a53bbfc-34c4-4dba-ad1c-c729391fd0ce'	System	05 Sep 2020 23:19:28
User entered '05 Sep 2020 18:19'	System	05 Sep 2020 23:19:28

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 7'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:55:09', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5fa84a34-edfb-4ee3-b6c6-6066a4b40d78' User entered 'Yes (Y)'	System	06 Sep 2020 22:55:57
	System	06 Sep 2020 22:55:57

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:55:50', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5fa84a34-edfb-4ee3-b6c6-6066a4b40d78' User entered '98.7'	System	06 Sep 2020 22:55:57
	System	06 Sep 2020 22:55:57

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:55:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5fa84a34-edfb-4ee3-b6c6-6066a4b40d78'	System	06 Sep 2020 22:55:57
User entered 'No (N)'	System	06 Sep 2020 22:55:57

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:55:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5fa84a34-edfb-4ee3-b6c6-6066a4b40d78'	System	06 Sep 2020 22:55:57
User entered '06 Sep 2020 17:55'	System	06 Sep 2020 22:55:57

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:26', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '06ffef0f-b15b-47b3-a8d2-1881337b4adc'	System	31 Aug 2020 17:34:08
User entered 'None (1)'	System	31 Aug 2020 17:34:08

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '06ffef0f-b15b-47b3-a8d2-1881337b4adc'	System	31 Aug 2020 17:34:08
User entered 'No (N)'	System	31 Aug 2020 17:34:08

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '06ffef0f-b15b-47b3-a8d2-1881337b4adc'	System	31 Aug 2020 17:34:08
User entered 'No (N)'	System	31 Aug 2020 17:34:08

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:16', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '06ffef0f-b15b-47b3-a8d2-1881337b4adc'	System	31 Aug 2020 17:34:08
User entered 'None (1)'	System	31 Aug 2020 17:34:08

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '06ffef0f-b15b-47b3-a8d2-1881337b4adc'	System	31 Aug 2020 17:34:08
User entered '31 Aug 2020 12:32'	System	31 Aug 2020 17:34:08

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 12:18'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 14:48'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:14:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e5ba8b17-aeb7-4b77-97be-abd36218876c' User entered 'None (1)'	System	31 Aug 2020 23:15:12
	System	31 Aug 2020 23:15:12

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:14:49', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e5ba8b17-aeb7-4b77-97be-abd36218876c' User entered 'No (N)'	System	31 Aug 2020 23:15:12
	System	31 Aug 2020 23:15:12

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:14:53', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e5ba8b17-aeb7-4b77-97be-abd36218876c' User entered 'No (N)'	System	31 Aug 2020 23:15:12
	System	31 Aug 2020 23:15:12

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e5ba8b17-aeb7-4b77-97be-abd36218876c' User entered 'None (1)'	System	31 Aug 2020 23:15:12
	System	31 Aug 2020 23:15:12

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e5ba8b17-aeb7-4b77-97be-abd36218876c' User entered '31 Aug 2020 18:15'	System	31 Aug 2020 23:15:12
	System	31 Aug 2020 23:15:12

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 15:43'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 2'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:39', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4b774ca1-40e6-4ed2-9904-3a135019804a' User entered 'None (1)'	System	01 Sep 2020 23:09:05
	System	01 Sep 2020 23:09:05

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4b774ca1-40e6-4ed2-9904-3a135019804a' User entered 'No (N)'	System	01 Sep 2020 23:09:05
	System	01 Sep 2020 23:09:05

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4b774ca1-40e6-4ed2-9904-3a135019804a' User entered 'No (N)'	System	01 Sep 2020 23:09:05
	System	01 Sep 2020 23:09:05

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:08:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4b774ca1-40e6-4ed2-9904-3a135019804a' User entered 'None (1)'	System	01 Sep 2020 23:09:05
	System	01 Sep 2020 23:09:05

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4b774ca1-40e6-4ed2-9904-3a135019804a' User entered '01 Sep 2020 18:09'	System	01 Sep 2020 23:09:05
	System	01 Sep 2020 23:09:05

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 3'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:19:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f856e6f9-cbbc-46a1-a602-f8f4c62eabc6'	System	03 Sep 2020 00:19:18
User entered 'None (1)'	System	03 Sep 2020 00:19:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:19:05', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f856e6f9-cbbc-46a1-a602-f8f4c62eabc6'	System	03 Sep 2020 00:19:18
User entered 'No (N)'	System	03 Sep 2020 00:19:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:19:09', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f856e6f9-cbbc-46a1-a602-f8f4c62eabc6'	System	03 Sep 2020 00:19:18
User entered 'No (N)'	System	03 Sep 2020 00:19:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:19:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f856e6f9-cbbc-46a1-a602-f8f4c62eabc6'	System	03 Sep 2020 00:19:18
User entered 'None (1)'	System	03 Sep 2020 00:19:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-02T19:19:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f856e6f9-cbbc-46a1-a602-f8f4c62eabc6'	System	03 Sep 2020 00:19:18
User entered '02 Sep 2020 19:19'	System	03 Sep 2020 00:19:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 4'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:57', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '886f2de4-bf27-4976-881a-e7621011f891' User entered 'None (1)'	System	03 Sep 2020 23:25:16
	System	03 Sep 2020 23:25:16

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:24:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '886f2de4-bf27-4976-881a-e7621011f891' User entered 'No (N)'	System	03 Sep 2020 23:25:16
	System	03 Sep 2020 23:25:16

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '886f2de4-bf27-4976-881a-e7621011f891' User entered 'No (N)'	System	03 Sep 2020 23:25:16
	System	03 Sep 2020 23:25:16

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '886f2de4-bf27-4976-881a-e7621011f891' User entered 'None (1)'	System	03 Sep 2020 23:25:16
	System	03 Sep 2020 23:25:16

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:14', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '886f2de4-bf27-4976-881a-e7621011f891' User entered '03 Sep 2020 18:25'	System	03 Sep 2020 23:25:16
	System	03 Sep 2020 23:25:16

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 5'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0363c930-d773-4dff-8686-a1f85b507293'	System	04 Sep 2020 23:33:51
User entered 'None (1)'	System	04 Sep 2020 23:33:51

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0363c930-d773-4dff-8686-a1f85b507293'	System	04 Sep 2020 23:33:51
User entered 'No (N)'	System	04 Sep 2020 23:33:51

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:26', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0363c930-d773-4dff-8686-a1f85b507293' User entered 'No (N)'	System	04 Sep 2020 23:33:51
	System	04 Sep 2020 23:33:51

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:45', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0363c930-d773-4dff-8686-a1f85b507293'	System	04 Sep 2020 23:33:51
User entered 'None (1)'	System	04 Sep 2020 23:33:51

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-04T18:33:48', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0363c930-d773-4dff-8686-a1f85b507293' User entered '04 Sep 2020 18:33'	System	04 Sep 2020 23:33:51
	System	04 Sep 2020 23:33:51

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 6'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20070e6b-fd6e-43d3-864c-99699a03e4c9'	System	05 Sep 2020 23:19:59
User entered 'None (1)'	System	05 Sep 2020 23:19:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:40', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20070e6b-fd6e-43d3-864c-99699a03e4c9' User entered 'No (N)'	System	05 Sep 2020 23:19:59
	System	05 Sep 2020 23:19:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20070e6b-fd6e-43d3-864c-99699a03e4c9' User entered 'No (N)'	System	05 Sep 2020 23:19:59
	System	05 Sep 2020 23:19:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:49', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20070e6b-fd6e-43d3-864c-99699a03e4c9' User entered 'None (1)'	System	05 Sep 2020 23:19:59
	System	05 Sep 2020 23:19:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:55', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20070e6b-fd6e-43d3-864c-99699a03e4c9'	System	05 Sep 2020 23:19:59
User entered '05 Sep 2020 18:19'	System	05 Sep 2020 23:19:59

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 7'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:55:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9cec8f2b-2583-4e59-b2ac-d258656a5e16' User entered 'None (1)'	System	06 Sep 2020 22:56:18
	System	06 Sep 2020 22:56:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:56:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9cec8f2b-2583-4e59-b2ac-d258656a5e16' User entered 'No (N)'	System	06 Sep 2020 22:56:18
	System	06 Sep 2020 22:56:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:56:07', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9cec8f2b-2583-4e59-b2ac-d258656a5e16' User entered 'No (N)'	System	06 Sep 2020 22:56:18
	System	06 Sep 2020 22:56:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:56:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9cec8f2b-2583-4e59-b2ac-d258656a5e16' User entered 'None (1)'	System	06 Sep 2020 22:56:18
	System	06 Sep 2020 22:56:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-06T17:56:16', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9cec8f2b-2583-4e59-b2ac-d258656a5e16'	System	06 Sep 2020 22:56:18
User entered '06 Sep 2020 17:56'	System	06 Sep 2020 22:56:18

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:33:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833'	System	31 Aug 2020 17:34:17
User entered 'None (0)'	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833' User entered 'None (0)'	System	31 Aug 2020 17:34:17
	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833' User entered 'None (0)'	System	31 Aug 2020 17:34:17
	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833' User entered 'None (0)'	System	31 Aug 2020 17:34:17
	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:56', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833' User entered 'None (0)'	System	31 Aug 2020 17:34:17
	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:32:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833' User entered 'None (0)'	System	31 Aug 2020 17:34:17
	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:33:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833'	System	31 Aug 2020 17:34:17
User entered 'No (N)'	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T12:33:09', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '1b91622f-8369-4254-8c6a-a76aa0e0c833'	System	31 Aug 2020 17:34:17
User entered '31 Aug 2020 12:33'	System	31 Aug 2020 17:34:17

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 12:18'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 14:48'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:18', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:26', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:36', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'None (0)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:43', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c' User entered 'No (N)'	System	31 Aug 2020 23:15:54
	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-08-31T18:15:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f5a6ee4f-b25d-4394-86e6-4c10438f896c'	System	31 Aug 2020 23:15:54
User entered '31 Aug 2020 18:15'	System	31 Aug 2020 23:15:54

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '31 Aug 2020 15:43'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 2'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:13', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:18', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:20', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'None (0)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:26', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered 'No (N)'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-01T18:09:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '57d08cf3-ff44-46f9-bf48-adb33e04820f' User entered '01 Sep 2020 18:09'	System	01 Sep 2020 23:09:35
	System	01 Sep 2020 23:09:35

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 3'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:27', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:29', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'None (0)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered 'No (N)'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T10:40:38', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'da4d192b-3d77-4494-a1a1-6699ea4b644f' User entered '03 Sep 2020 10:40'	System	03 Sep 2020 15:40:41
	System	03 Sep 2020 15:40:41

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 4'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:20', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:22', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:26:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:36', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'None (0)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:25:45', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered 'No (N)'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-03T18:26:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0eb35d03-db12-4980-a08e-7ba7a7d5187c' User entered '03 Sep 2020 18:26'	System	03 Sep 2020 23:26:37
	System	03 Sep 2020 23:26:37

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 5'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 6'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:19:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:05', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'None (0)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered 'No (N)'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-05T18:20:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'be82b4fe-2935-495c-ae6c-c815858ac4fe' User entered '05 Sep 2020 18:20'	System	05 Sep 2020 23:20:30
	System	05 Sep 2020 23:20:30

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 7'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:03:07

US3312395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:24
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered 'Yes (Y)'	(b) (4)	11 Sep 2020 22:48:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:24
User closed query 'Source states day 8 call occurred on 7Sep2020. Please verify and update. Thanks ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:12:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
Query 'Source states day 8 call occurred on 7Sep2020. Please verify and update. Thanks ' answered with 'CORRECT AS ENTERED. 07SEP2020 WAS THE DATE OF THE FIRST ATTEMPT, NOT DATE CALL WAS COMPLETED.' (Site from CRA).	(b) (4) Karol Moore (b) (4) (b) (4)	17 Nov 2020 20:45:14
User opened query 'Source states day 8 call occurred on 7Sep2020. Please verify and update. Thanks ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:15:08
User entered '8 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:48:09

US3312395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:24
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:48:09

US3312395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:13:24
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:48:09

US3312395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:15:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 22:48:15

US3312395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'I'	System	11 Sep 2020 22:48:15

US3312395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:17:29
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:33

US3312395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:17:29
User entered '14 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:33

US3312395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:17:29
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:33

US3312395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:17:29
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:33

US3312395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:18:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:37

US3312395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'I'	System	23 Sep 2020 19:11:37

US3312395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:48

US3312395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:12
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:48

US3312395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:12
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:48

US3312395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:12
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:48

US3312395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:11:51

US3312395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:23:53
User entered 'I'	System	23 Sep 2020 19:11:51

US3312395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:18:00

US3312395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:35
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:18:00

US3312395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:19:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Sep 2020 16:18:00

US3312395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'VISIT2'	System	28 Sep 2020 16:18:00

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '28 Sep 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '10:08'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '28 Sep 2020 10:08'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '98.0' F	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '59'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'bpm'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '16'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'breaths/min'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '135'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '88'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '28 Sep 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '11:44'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '28 Sep 2020 11:44'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '98.4' F	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '57'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'bpm'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '14'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'breaths/min'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '129'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:02
User entered '82'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	18 Oct 2020 00:24:15

US3312395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:31
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:23

US3312395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:31
User entered '28 Sep 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:23

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered '11:13'	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '28 Sep 2020 11:13'	System	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:51
User entered 'ONCE'	System	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 16:18:35

US3312395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:34
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:38

US3312395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:34
User entered '28 Sep 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:38

US3312395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:34
User entered '10:37'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:38

US3312395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '28 Sep 2020 10:37'	System	18 Oct 2020 00:24:38

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:56
User entered '28 Sep 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:56
User entered '10:29'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '28 Sep 2020 10:29'	System	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:56
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered empty.	System	18 Oct 2020 00:24:48

US3312395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:18:44

US3312395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	28 Sep 2020 16:18:44

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a5e4046c-3d8c-461a-93c1-05e745ba9182' User entered 'Yes (Y)'	System	28 Sep 2020 16:46:22
	System	28 Sep 2020 16:46:22

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a5e4046c-3d8c-461a-93c1-05e745ba9182' User entered '98.4'	System	28 Sep 2020 16:46:22
	System	28 Sep 2020 16:46:22

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:05', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a5e4046c-3d8c-461a-93c1-05e745ba9182'	System	28 Sep 2020 16:46:22
User entered 'No (N)'	System	28 Sep 2020 16:46:22

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a5e4046c-3d8c-461a-93c1-05e745ba9182'	System	28 Sep 2020 16:46:22
User entered '28 Sep 2020 11:46'	System	28 Sep 2020 16:46:22

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 11:33'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 14:03'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:12:55', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd680cf5b-80fe-458a-840f-3f1c6d39f01a' User entered 'Yes (Y)'	System	28 Sep 2020 20:13:20
	System	28 Sep 2020 20:13:20

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd680cf5b-80fe-458a-840f-3f1c6d39f01a' User entered '97.6'	System	28 Sep 2020 20:13:20
	System	28 Sep 2020 20:13:20

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:13', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd680cf5b-80fe-458a-840f-3f1c6d39f01a'	System	28 Sep 2020 20:13:20
User entered 'No (N)'	System	28 Sep 2020 20:13:20

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:17', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd680cf5b-80fe-458a-840f-3f1c6d39f01a' User entered '28 Sep 2020 15:13'	System	28 Sep 2020 20:13:20
	System	28 Sep 2020 20:13:20

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 14:58'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 2'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:08:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '727a5382-470b-42ac-91b5-34c956f9e945'	System	30 Sep 2020 23:02:40
User entered 'Yes (Y)'	System	30 Sep 2020 23:02:40

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:08:55', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '727a5382-470b-42ac-91b5-34c956f9e945' User entered '97.6'	System	30 Sep 2020 23:02:40
	System	30 Sep 2020 23:02:40

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:08:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '727a5382-470b-42ac-91b5-34c956f9e945'	System	30 Sep 2020 23:02:40
User entered 'No (N)'	System	30 Sep 2020 23:02:40

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '727a5382-470b-42ac-91b5-34c956f9e945'	System	30 Sep 2020 23:02:40
User entered '29 Sep 2020 17:09'	System	30 Sep 2020 23:02:40

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 3'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:02:39', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'c70da3db-0759-4675-ad33-f40b7fa19423' User entered 'Yes (Y)'	System	30 Sep 2020 23:02:58
	System	30 Sep 2020 23:02:58

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:02:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'c70da3db-0759-4675-ad33-f40b7fa19423' User entered '97.0'	System	30 Sep 2020 23:02:58
	System	30 Sep 2020 23:02:58

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:02:50', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'c70da3db-0759-4675-ad33-f40b7fa19423'	System	30 Sep 2020 23:02:58
User entered 'No (N)'	System	30 Sep 2020 23:02:58

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:02:53', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'c70da3db-0759-4675-ad33-f40b7fa19423' User entered '30 Sep 2020 18:02'	System	30 Sep 2020 23:02:58
	System	30 Sep 2020 23:02:58

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 4'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:16', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'b71d4a47-5ad6-46e2-bd04-c553230c2d18' User entered 'Yes (Y)'	System	01 Oct 2020 21:05:30
	System	01 Oct 2020 21:05:30

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'b71d4a47-5ad6-46e2-bd04-c553230c2d18' User entered '97.7'	System	01 Oct 2020 21:05:30
	System	01 Oct 2020 21:05:30

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'b71d4a47-5ad6-46e2-bd04-c553230c2d18'	System	01 Oct 2020 21:05:30
User entered 'No (N)'	System	01 Oct 2020 21:05:30

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:28', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'b71d4a47-5ad6-46e2-bd04-c553230c2d18'	System	01 Oct 2020 21:05:30
User entered '01 Oct 2020 16:05'	System	01 Oct 2020 21:05:30

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 5'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:32:56', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '8f346048-4caf-48c7-885b-fd226ae2eeb4' User entered 'No (N)'	System	02 Oct 2020 21:33:08
	System	02 Oct 2020 21:33:08

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '8f346048-4caf-48c7-885b-fd226ae2eeb4'	System	02 Oct 2020 21:33:08
User entered 'No (N)'	System	02 Oct 2020 21:33:08

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '8f346048-4caf-48c7-885b-fd226ae2eeb4' User entered '02 Oct 2020 16:33'	System	02 Oct 2020 21:33:08
	System	02 Oct 2020 21:33:08

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 6'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:37:40', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fdb0-699d-441d-9076-d3f12e20e3ad'	System	04 Oct 2020 00:37:57
User entered 'Yes (Y)'	System	04 Oct 2020 00:37:57

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:37:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fdbe1b0-699d-441d-9076-d3f12e20e3ad' User entered '99.6'	System	04 Oct 2020 00:37:57
	System	04 Oct 2020 00:37:57

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:37:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fdbe1b0-699d-441d-9076-d3f12e20e3ad'	System	04 Oct 2020 00:37:57
User entered 'No (N)'	System	04 Oct 2020 00:37:57

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:37:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fdbe1b0-699d-441d-9076-d3f12e20e3ad' User entered '03 Oct 2020 19:37'	System	04 Oct 2020 00:37:57
	System	04 Oct 2020 00:37:57

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 7'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:38:55', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '729a6e86-27f3-4dfd-b8d6-7aaf917f9c8b' User entered 'Yes (Y)'	System	05 Oct 2020 16:39:17
	System	05 Oct 2020 16:39:17

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '729a6e86-27f3-4dfd-b8d6-7aaf917f9c8b' User entered '99.6'	System	05 Oct 2020 16:39:17
	System	05 Oct 2020 16:39:17

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '729a6e86-27f3-4dfd-b8d6-7aaf917f9c8b'	System	05 Oct 2020 16:39:17
User entered 'No (N)'	System	05 Oct 2020 16:39:17

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '729a6e86-27f3-4dfd-b8d6-7aaf917f9c8b' User entered '05 Oct 2020 11:39'	System	05 Oct 2020 16:39:17
	System	05 Oct 2020 16:39:17

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:25', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e2e55895-80cb-4941-8a11-702af8491f88'	System	28 Sep 2020 16:46:38
User entered 'None (1)'	System	28 Sep 2020 16:46:38

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:28', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e2e55895-80cb-4941-8a11-702af8491f88'	System	28 Sep 2020 16:46:38
User entered 'No (N)'	System	28 Sep 2020 16:46:38

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e2e55895-80cb-4941-8a11-702af8491f88'	System	28 Sep 2020 16:46:38
User entered 'No (N)'	System	28 Sep 2020 16:46:38

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:32', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e2e55895-80cb-4941-8a11-702af8491f88'	System	28 Sep 2020 16:46:38
User entered 'None (1)'	System	28 Sep 2020 16:46:38

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:35', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e2e55895-80cb-4941-8a11-702af8491f88'	System	28 Sep 2020 16:46:38
User entered '28 Sep 2020 11:46'	System	28 Sep 2020 16:46:38

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 11:33'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 14:03'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:23', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a61da3af-25f6-4e72-bbd4-daf76caa33b8'	System	28 Sep 2020 20:13:37
User entered 'None (1)'	System	28 Sep 2020 20:13:37

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:27', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a61da3af-25f6-4e72-bbd4-daf76caa33b8' User entered 'No (N)'	System	28 Sep 2020 20:13:37
	System	28 Sep 2020 20:13:37

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:30', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a61da3af-25f6-4e72-bbd4-daf76caa33b8' User entered 'No (N)'	System	28 Sep 2020 20:13:37
	System	28 Sep 2020 20:13:37

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:33', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a61da3af-25f6-4e72-bbd4-daf76caa33b8' User entered 'None (1)'	System	28 Sep 2020 20:13:37
	System	28 Sep 2020 20:13:37

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:13:36', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a61da3af-25f6-4e72-bbd4-daf76caa33b8' User entered '28 Sep 2020 15:13'	System	28 Sep 2020 20:13:37
	System	28 Sep 2020 20:13:37

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '28 Sep 2020 14:58'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 2'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7040b9a2-8bd3-446d-8752-506e346f0115'	System	30 Sep 2020 23:02:41
User entered 'None (1)'	System	30 Sep 2020 23:02:41

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7040b9a2-8bd3-446d-8752-506e346f0115' User entered 'No (N)'	System	30 Sep 2020 23:02:41
	System	30 Sep 2020 23:02:41

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7040b9a2-8bd3-446d-8752-506e346f0115' User entered 'No (N)'	System	30 Sep 2020 23:02:41
	System	30 Sep 2020 23:02:41

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7040b9a2-8bd3-446d-8752-506e346f0115'	System	30 Sep 2020 23:02:41
User entered 'None (1)'	System	30 Sep 2020 23:02:41

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7040b9a2-8bd3-446d-8752-506e346f0115'	System	30 Sep 2020 23:02:41
User entered '29 Sep 2020 17:09'	System	30 Sep 2020 23:02:41

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 3'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:02:57', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '902a8b58-b90c-4f1b-940a-c5c3c1942480' User entered 'None (1)'	System	30 Sep 2020 23:03:13
	System	30 Sep 2020 23:03:13

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '902a8b58-b90c-4f1b-940a-c5c3c1942480' User entered 'No (N)'	System	30 Sep 2020 23:03:13
	System	30 Sep 2020 23:03:13

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '902a8b58-b90c-4f1b-940a-c5c3c1942480' User entered 'No (N)'	System	30 Sep 2020 23:03:13
	System	30 Sep 2020 23:03:13

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '902a8b58-b90c-4f1b-940a-c5c3c1942480' User entered 'None (1)'	System	30 Sep 2020 23:03:13
	System	30 Sep 2020 23:03:13

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '902a8b58-b90c-4f1b-940a-c5c3c1942480' User entered '30 Sep 2020 18:03'	System	30 Sep 2020 23:03:13
	System	30 Sep 2020 23:03:13

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 4'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:35', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '312f59c9-d973-47ed-9615-5865f42b6ba4' User entered 'None (1)'	System	01 Oct 2020 21:05:56
	System	01 Oct 2020 21:05:56

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:40', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '312f59c9-d973-47ed-9615-5865f42b6ba4' User entered 'No (N)'	System	01 Oct 2020 21:05:56
	System	01 Oct 2020 21:05:56

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:43', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '312f59c9-d973-47ed-9615-5865f42b6ba4' User entered 'No (N)'	System	01 Oct 2020 21:05:56
	System	01 Oct 2020 21:05:56

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:50', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '312f59c9-d973-47ed-9615-5865f42b6ba4' User entered 'None (1)'	System	01 Oct 2020 21:05:56
	System	01 Oct 2020 21:05:56

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:05:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '312f59c9-d973-47ed-9615-5865f42b6ba4' User entered '01 Oct 2020 16:05'	System	01 Oct 2020 21:05:56
	System	01 Oct 2020 21:05:56

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 5'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:11', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd29ad576-7347-4c91-9539-274a74b85868'	System	02 Oct 2020 21:33:27
User entered 'None (1)'	System	02 Oct 2020 21:33:27

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd29ad576-7347-4c91-9539-274a74b85868' User entered 'No (N)'	System	02 Oct 2020 21:33:27
	System	02 Oct 2020 21:33:27

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:18', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd29ad576-7347-4c91-9539-274a74b85868' User entered 'No (N)'	System	02 Oct 2020 21:33:27
	System	02 Oct 2020 21:33:27

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd29ad576-7347-4c91-9539-274a74b85868'	System	02 Oct 2020 21:33:27
User entered 'None (1)'	System	02 Oct 2020 21:33:27

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:25', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'd29ad576-7347-4c91-9539-274a74b85868' User entered '02 Oct 2020 16:33'	System	02 Oct 2020 21:33:27
	System	02 Oct 2020 21:33:27

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 6'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:37:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a928e75a-eb82-483a-98c4-47ee28e7bf40' User entered 'None (1)'	System	04 Oct 2020 00:38:14
	System	04 Oct 2020 00:38:14

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a928e75a-eb82-483a-98c4-47ee28e7bf40' User entered 'No (N)'	System	04 Oct 2020 00:38:14
	System	04 Oct 2020 00:38:14

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:05', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a928e75a-eb82-483a-98c4-47ee28e7bf40'	System	04 Oct 2020 00:38:14
User entered 'No (N)'	System	04 Oct 2020 00:38:14

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:08', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a928e75a-eb82-483a-98c4-47ee28e7bf40'	System	04 Oct 2020 00:38:14
User entered 'None (1)'	System	04 Oct 2020 00:38:14

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:11', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a928e75a-eb82-483a-98c4-47ee28e7bf40' User entered '03 Oct 2020 19:38'	System	04 Oct 2020 00:38:14
	System	04 Oct 2020 00:38:14

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 7'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:14', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10b2492d-85ca-4035-8a1e-467a52b722cf'	System	05 Oct 2020 16:39:30
User entered 'None (1)'	System	05 Oct 2020 16:39:30

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:18', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10b2492d-85ca-4035-8a1e-467a52b722cf' User entered 'No (N)'	System	05 Oct 2020 16:39:30
	System	05 Oct 2020 16:39:30

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:21', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10b2492d-85ca-4035-8a1e-467a52b722cf' User entered 'No (N)'	System	05 Oct 2020 16:39:30
	System	05 Oct 2020 16:39:30

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10b2492d-85ca-4035-8a1e-467a52b722cf'	System	05 Oct 2020 16:39:30
User entered 'None (1)'	System	05 Oct 2020 16:39:30

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:28', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '10b2492d-85ca-4035-8a1e-467a52b722cf' User entered '05 Oct 2020 11:39'	System	05 Oct 2020 16:39:30
	System	05 Oct 2020 16:39:30

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:43', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:45', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:49', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'None (0)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:56', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered 'No (N)'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T11:46:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'e839a009-0b3a-4a41-8daa-3b1481d321de' User entered '28 Sep 2020 11:46'	System	28 Sep 2020 16:47:02
	System	28 Sep 2020 16:47:02

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '28 Sep 2020 11:33'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '28 Sep 2020 14:03'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:38', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:40', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:48', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:56', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'None (0)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:14:57', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered 'No (N)'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-28T15:15:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '41e5e20e-0e18-4d8a-b622-a02464ca9b21' User entered '28 Sep 2020 15:15'	System	28 Sep 2020 20:15:07
	System	28 Sep 2020 20:15:07

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '28 Sep 2020 14:58'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 2'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:25', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:28', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:34', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:36', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:38', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'None (0)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered 'No (N)'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-29T17:09:43', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0ca2815e-c1fc-4b7d-b479-99c3f548aba3' User entered '29 Sep 2020 17:09'	System	30 Sep 2020 23:02:44
	System	30 Sep 2020 23:02:44

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 3'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:13', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:25', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:27', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:29', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'None (0)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:32', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered 'No (N)'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-09-30T18:03:35', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a0099e84-2a34-4a43-b94c-4f47cd7b9ed3' User entered '30 Sep 2020 18:03'	System	30 Sep 2020 23:03:39
	System	30 Sep 2020 23:03:39

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 4'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:04', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:09', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:14', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'None (0)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:17', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered 'No (N)'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-01T16:06:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '99a998d4-13d0-4993-91e3-a8a1583f7856' User entered '01 Oct 2020 16:06'	System	01 Oct 2020 21:06:22
	System	01 Oct 2020 21:06:22

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 5'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffffed47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:34', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffff47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:37', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffffed47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffffed47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffff47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffff47-ebd6-4621-bb65-629542e51a31' User entered 'None (0)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffffed47-ebd6-4621-bb65-629542e51a31' User entered 'No (N)'	System	02 Oct 2020 21:33:56
	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-02T16:33:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'dffff47-ebd6-4621-bb65-629542e51a31'	System	02 Oct 2020 21:33:56
User entered '02 Oct 2020 16:33'	System	02 Oct 2020 21:33:56

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 6'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:15', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:17', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:19', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:22', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:27', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:35', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'None (0)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered 'No (N)'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-03T19:38:49', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '4d29ced7-90ea-41b9-ad78-b19603c7d473' User entered '03 Oct 2020 19:38'	System	04 Oct 2020 00:38:51
	System	04 Oct 2020 00:38:51

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
Data entry locked.	System	28 Sep 2020 16:18:35
User entered 'Day 7'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:32', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:34', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:36', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:41', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'None (0)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:50', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered 'No (N)'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-10-05T11:39:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '27ef047f-0498-44d0-94f4-c5da660d0614' User entered '05 Oct 2020 11:39'	System	05 Oct 2020 16:39:58
	System	05 Oct 2020 16:39:58

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:18:35

US3312395

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:40
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:18:35

US3312395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:16

US3312395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:40
User entered '05 Oct 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:16

US3312395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:40
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:16

US3312395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:40
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:16

US3312395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:37:52
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:20

US3312395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	18 Oct 2020 00:25:20

US3312395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:38

US3312395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:30
User entered '12 Oct 2020'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:38

US3312395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:30
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:38

US3312395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:30
User entered empty.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:38

US3312395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:34
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 00:25:41

US3312395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	18 Oct 2020 00:25:41

US3312395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:48:35

US3312395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:45
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:48:35

US3312395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 16:48:35

US3312395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:38:45
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:48:35

US3312395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:39:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:48:38

US3312395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	20 Oct 2020 16:48:38

US3312395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:18:37

US3312395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:39:32
User entered '26 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:18:37

US3312395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:39:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 20:18:37

US3312395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'VISIT3'	System	28 Oct 2020 20:18:37

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '26 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '10:00'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '26 Oct 2020 10:00'	System	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '98.2' F	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '58'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'bpm'	System	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '12'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'breaths/min'	System	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '108'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:30
User entered '65'	(b) (4), (b) (6)	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'mmHg'	System	28 Oct 2020 20:18:58

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04

US3312395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04

US3312395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:39
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:19:04

US3312395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:42:39
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:19:04

US3312395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:43:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:19:14

US3312395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:43:10
User entered '26 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:19:14

US3312395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:43:10
User entered '10:09'	(b) (4), (b) (6)	28 Oct 2020 20:19:14

US3312395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered '26 Oct 2020 10:09'	System	28 Oct 2020 20:19:14

US3312395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:45:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:17:53

US3312395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	28 Oct 2020 20:17:53

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 64'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-01T09:08:39', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '55b84c2c-298e-4c78-8526-00f4f3617c0e' User entered 'No (N)'	System	01 Nov 2020 15:08:58
	System	01 Nov 2020 15:08:58

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-01T09:08:44', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '55b84c2c-298e-4c78-8526-00f4f3617c0e' User entered 'No (N)'	System	01 Nov 2020 15:08:58
	System	01 Nov 2020 15:08:58

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-01T09:08:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '55b84c2c-298e-4c78-8526-00f4f3617c0e' User entered '01 Nov 2020 09:08:54'	System	01 Nov 2020 15:08:58
	System	01 Nov 2020 15:08:58

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 71'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-09T17:28:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '819acda7-5420-4347-a6ff-2735d96f8b37'	System	09 Nov 2020 23:29:11
User entered 'No (N)'	System	09 Nov 2020 23:29:11

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-09T17:29:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '819acda7-5420-4347-a6ff-2735d96f8b37'	System	09 Nov 2020 23:29:11
User entered 'No (N)'	System	09 Nov 2020 23:29:11

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-09T17:29:07', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '819acda7-5420-4347-a6ff-2735d96f8b37' User entered '09 Nov 2020 17:29:07'	System	09 Nov 2020 23:29:11
	System	09 Nov 2020 23:29:11

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered 'Day 78'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-16T09:09:51', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '77086d40-91df-4a9a-a042-1d027251c0bb' User entered 'No (N)'	System	16 Nov 2020 15:10:12
	System	16 Nov 2020 15:10:12

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-16T09:10:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '77086d40-91df-4a9a-a042-1d027251c0bb' User entered 'No (N)'	System	16 Nov 2020 15:10:12
	System	16 Nov 2020 15:10:12

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-16T09:10:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '77086d40-91df-4a9a-a042-1d027251c0bb' User entered '16 Nov 2020 09:10:10'	System	16 Nov 2020 15:10:12
	System	16 Nov 2020 15:10:12

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 17:03:07

US3312395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:04:50
Data entry locked.	System	31 Aug 2020 17:03:07
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 17:03:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-27T08:23:47', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7a00ece9-4030-4766-aba0-1633c7d178ee' User entered 'No (N)'	System	27 Nov 2020 14:23:58
	System	27 Nov 2020 14:23:58

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-27T08:23:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7a00ece9-4030-4766-aba0-1633c7d178ee' User entered 'No (N)'	System	27 Nov 2020 14:23:58
	System	27 Nov 2020 14:23:58

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-11-27T08:23:55', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7a00ece9-4030-4766-aba0-1633c7d178ee' User entered '27 Nov 2020 08:23:55'	System	27 Nov 2020 14:23:58
	System	27 Nov 2020 14:23:58

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-02T08:37:29', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '828f6d6f-180f-4b60-a147-01167912c9db' User entered 'No (N)'	System	02 Dec 2020 14:37:44
	System	02 Dec 2020 14:37:44

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-02T08:37:39', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '828f6d6f-180f-4b60-a147-01167912c9db' User entered 'No (N)'	System	02 Dec 2020 14:37:44
	System	02 Dec 2020 14:37:44

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-02T08:37:42', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '828f6d6f-180f-4b60-a147-01167912c9db' User entered '02 Dec 2020 08:37:42'	System	02 Dec 2020 14:37:44
	System	02 Dec 2020 14:37:44

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-09T08:07:46', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a8b1a086-77b5-46d5-83ec-be59fddbe5d3' User entered 'No (N)'	System	09 Dec 2020 14:08:04
	System	09 Dec 2020 14:08:04

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-09T08:07:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a8b1a086-77b5-46d5-83ec-be59fddbe5d3' User entered 'No (N)'	System	09 Dec 2020 14:08:04
	System	09 Dec 2020 14:08:04

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-09T08:07:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a8b1a086-77b5-46d5-83ec-be59fddbe5d3' User entered '09 Dec 2020 08:07:58'	System	09 Dec 2020 14:08:04
	System	09 Dec 2020 14:08:04

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-16T07:23:52', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'abfdeb35-d919-47d7-995a-44debc6da8b5'	System	16 Dec 2020 13:24:08
User entered 'No (N)'	System	16 Dec 2020 13:24:08

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-16T07:23:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'abfdeb35-d919-47d7-995a-44debc6da8b5' User entered 'No (N)'	System	16 Dec 2020 13:24:08

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-16T07:24:01', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'abfdeb35-d919-47d7-995a-44debc6da8b5' User entered '16 Dec 2020 07:24:01'	System	16 Dec 2020 13:24:08
	System	16 Dec 2020 13:24:08

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-23T09:31:46', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fb39dfd-8b60-497d-8f5e-069e35051fae' User entered 'No (N)'	System	23 Dec 2020 15:32:07
	System	23 Dec 2020 15:32:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-23T09:31:54', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fb39dfd-8b60-497d-8f5e-069e35051fae' User entered 'No (N)'	System	23 Dec 2020 15:32:07
	System	23 Dec 2020 15:32:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2020-12-23T09:32:04', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '3fb39dfd-8b60-497d-8f5e-069e35051fae' User entered '23 Dec 2020 09:32:04'	System	23 Dec 2020 15:32:07
	System	23 Dec 2020 15:32:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-02T13:11:03', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20f8e39f-2fd2-4b78-b764-6030ac63c966'	System	02 Jan 2021 19:11:16
User entered 'No (N)'	System	02 Jan 2021 19:11:16

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-02T13:11:06', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20f8e39f-2fd2-4b78-b764-6030ac63c966'	System	02 Jan 2021 19:11:16
User entered 'No (N)'	System	02 Jan 2021 19:11:16

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-02T13:11:10', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '20f8e39f-2fd2-4b78-b764-6030ac63c966'	System	02 Jan 2021 19:11:16
User entered '02 Jan 2021 13:11:10'	System	02 Jan 2021 19:11:16

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-06T08:07:20', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5e441509-af57-4cdf-bb82-d81b96651851' User entered 'No (N)'	System	06 Jan 2021 14:07:35
	System	06 Jan 2021 14:07:35

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-06T08:07:27', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5e441509-af57-4cdf-bb82-d81b96651851' User entered 'No (N)'	System	06 Jan 2021 14:07:35

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-06T08:07:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5e441509-af57-4cdf-bb82-d81b96651851' User entered '06 Jan 2021 08:07:31'	System	06 Jan 2021 14:07:35
	System	06 Jan 2021 14:07:35

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-13T08:05:49', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f603d3bb-a676-462f-aebf-19b96f050dd4'	System	13 Jan 2021 14:06:07
User entered 'No (N)'	System	13 Jan 2021 14:06:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-13T08:05:58', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f603d3bb-a676-462f-aebf-19b96f050dd4'	System	13 Jan 2021 14:06:07
User entered 'No (N)'	System	13 Jan 2021 14:06:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-13T08:06:02', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f603d3bb-a676-462f-aebf-19b96f050dd4' User entered '13 Jan 2021 08:06:02'	System	13 Jan 2021 14:06:07
	System	13 Jan 2021 14:06:07

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-21T08:36:04', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a54993f6-f2af-402f-b298-2cb1f9ccef55'	System	21 Jan 2021 14:37:02
User entered 'Yes (Y)'	System	21 Jan 2021 14:37:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-21T08:36:12', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a54993f6-f2af-402f-b298-2cb1f9cce55'	System	21 Jan 2021 14:37:02
User entered 'No (N)'	System	21 Jan 2021 14:37:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-21T08:36:17', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a54993f6-f2af-402f-b298-2cb1f9cce55'	System	21 Jan 2021 14:37:02
User entered 'No (N)'	System	21 Jan 2021 14:37:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-21T08:36:31', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a54993f6-f2af-402f-b298-2cb1f9cce55'	System	21 Jan 2021 14:37:02
User entered 'No (N)'	System	21 Jan 2021 14:37:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-21T08:36:59', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'a54993f6-f2af-402f-b298-2cb1f9cce55'	System	21 Jan 2021 14:37:02
User entered '21 Jan 2021 08:36:59'	System	21 Jan 2021 14:37:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-27T19:31:24', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '370e11d5-c59a-4761-bcff-302ce640cabe' User entered 'No (N)'	System	28 Jan 2021 01:31:37
	System	28 Jan 2021 01:31:37

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-27T19:31:29', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '370e11d5-c59a-4761-bcff-302ce640cabe' User entered 'No (N)'	System	28 Jan 2021 01:31:37
	System	28 Jan 2021 01:31:37

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-01-27T19:31:32', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '370e11d5-c59a-4761-bcff-302ce640cabe' User entered '27 Jan 2021 19:31:32'	System	28 Jan 2021 01:31:37

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-17T16:55:40', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5b886a03-68b4-44fb-ba9d-7471689b742c' User entered 'No (N)'	System	17 Feb 2021 22:56:02
	System	17 Feb 2021 22:56:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-17T16:55:53', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5b886a03-68b4-44fb-ba9d-7471689b742c' User entered 'No (N)'	System	17 Feb 2021 22:56:02
	System	17 Feb 2021 22:56:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-17T16:56:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '5b886a03-68b4-44fb-ba9d-7471689b742c' User entered '17 Feb 2021 16:56:00'	System	17 Feb 2021 22:56:02
	System	17 Feb 2021 22:56:02

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-24T08:34:08-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7cf21374-9ebc-4d5a-89f0-79963920c226'	System	24 Feb 2021 14:34:24
User entered 'No (N)'	System	24 Feb 2021 14:34:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-24T08:34:13-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7cf21374-9ebc-4d5a-89f0-79963920c226'	System	24 Feb 2021 14:34:24
User entered 'No (N)'	System	24 Feb 2021 14:34:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-02-24T08:34:17-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '7cf21374-9ebc-4d5a-89f0-79963920c226'	System	24 Feb 2021 14:34:24
User entered '24 Feb 2021 14:34:17'	System	24 Feb 2021 14:34:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-10T09:55:44-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f48a2a9c-211e-4dd2-8d4b-75791c2eccd4'	System	10 Mar 2021 15:56:03
User entered 'No (N)'	System	10 Mar 2021 15:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-10T09:55:49-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f48a2a9c-211e-4dd2-8d4b-75791c2eccd4'	System	10 Mar 2021 15:56:03
User entered 'No (N)'	System	10 Mar 2021 15:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-10T09:55:52-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'f48a2a9c-211e-4dd2-8d4b-75791c2eccd4' User entered '10 Mar 2021 09:55:52'	System	10 Mar 2021 15:56:03
	System	10 Mar 2021 15:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-17T18:05:07-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'df43cfd9-4f6e-4043-9700-840cdc0ca5f2'	System	17 Mar 2021 23:06:31
User entered 'No (N)'	System	17 Mar 2021 23:06:31

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-17T18:05:11-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'df43cfd9-4f6e-4043-9700-840cdc0ca5f2'	System	17 Mar 2021 23:06:31
User entered 'No (N)'	System	17 Mar 2021 23:06:31

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-17T18:05:16-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'df43cfd9-4f6e-4043-9700-840cdc0ca5f2'	System	17 Mar 2021 23:06:31
User entered '17 Mar 2021 18:05:16'	System	17 Mar 2021 23:06:31

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-24T15:50:47-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9c68b5c3-adcf-4173-a200-305cb0d1b70b'	System	24 Mar 2021 20:51:01
User entered 'No (N)'	System	24 Mar 2021 20:51:01

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-24T15:50:52-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9c68b5c3-adcf-4173-a200-305cb0d1b70b'	System	24 Mar 2021 20:51:01
User entered 'No (N)'	System	24 Mar 2021 20:51:01

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-24T15:50:56-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '9c68b5c3-adcf-4173-a200-305cb0d1b70b' User entered '24 Mar 2021 15:50:56'	System	24 Mar 2021 20:51:01
	System	24 Mar 2021 20:51:01

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-03T08:29:05-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0c5e5669-2136-4441-89ef-7f40427210ca' User entered 'No (N)'	System	03 Apr 2021 13:29:24
	System	03 Apr 2021 13:29:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-03T08:29:15-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0c5e5669-2136-4441-89ef-7f40427210ca' User entered 'No (N)'	System	03 Apr 2021 13:29:24
	System	03 Apr 2021 13:29:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-03T08:29:19-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '0c5e5669-2136-4441-89ef-7f40427210ca' User entered '03 Apr 2021 08:29:19'	System	03 Apr 2021 13:29:24
	System	03 Apr 2021 13:29:24

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-08T08:05:36-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'fc48e65d-dbf8-49e9-9b04-b748172bb023'	System	08 Apr 2021 13:05:45
User entered 'No (N)'	System	08 Apr 2021 13:05:45

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-08T08:05:39-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'fc48e65d-dbf8-49e9-9b04-b748172bb023'	System	08 Apr 2021 13:05:45
User entered 'No (N)'	System	08 Apr 2021 13:05:45

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-08T08:05:42-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: 'fc48e65d-dbf8-49e9-9b04-b748172bb023'	System	08 Apr 2021 13:05:45
User entered '08 Apr 2021 08:05:42'	System	08 Apr 2021 13:05:45

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-14T22:13:02-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '43b48332-348b-4455-b864-d0aac1e38291'	System	15 Apr 2021 03:13:12
User entered 'No (N)'	System	15 Apr 2021 03:13:12

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-14T22:13:07-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '43b48332-348b-4455-b864-d0aac1e38291'	System	15 Apr 2021 03:13:12
User entered 'No (N)'	System	15 Apr 2021 03:13:12

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-14T22:13:10-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '43b48332-348b-4455-b864-d0aac1e38291'	System	15 Apr 2021 03:13:12
User entered '14 Apr 2021 22:13:10'	System	15 Apr 2021 03:13:12

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-21T18:42:12-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '755303d4-3f4f-4aeb-9533-c78cebcf75c8'	System	21 Apr 2021 23:42:25
User entered 'No (N)'	System	21 Apr 2021 23:42:25

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-21T18:42:16-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '755303d4-3f4f-4aeb-9533-c78cebcf75c8'	System	21 Apr 2021 23:42:25
User entered 'No (N)'	System	21 Apr 2021 23:42:25

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-21T18:42:20-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '755303d4-3f4f-4aeb-9533-c78cebcf75c8'	System	21 Apr 2021 23:42:25
User entered '21 Apr 2021 18:42:20'	System	21 Apr 2021 23:42:25

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-28T11:37:52-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '49c233ee-1bf9-4a89-a7e1-c2e65c84ae6b' User entered 'No (N)'	System	28 Apr 2021 23:47:41
	System	28 Apr 2021 23:47:41

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

Have you been exposed to someone with 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 (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-28T11:37:56-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '49c233ee-1bf9-4a89-a7e1-c2e65c84ae6b' User entered 'No (N)'	System	28 Apr 2021 23:47:41
	System	28 Apr 2021 23:47:41

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-04-28T11:38:00-05:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '49c233ee-1bf9-4a89-a7e1-c2e65c84ae6b' User entered '28 Apr 2021 11:38:00'	System	28 Apr 2021 23:47:41
	System	28 Apr 2021 23:47:41

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:56:03

US3312395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:56:03
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:56:03

US3312395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:01:36

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 17:14:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-10T09:56:12-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '04684ad1-67b8-4e86-861b-66091e8d91b6'	System	10 Mar 2021 15:56:31
User entered 'No (N)'	System	10 Mar 2021 15:56:31

US3312395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:01:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:14:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA277B2E-671B-4747-97CA-73760F199A3B)', Time: '2021-03-10T09:56:28-06:00', User OID: 'PatientReportedOutcome (US3312395)', ODM File OID: '04684ad1-67b8-4e86-861b-66091e8d91b6'	System	10 Mar 2021 15:56:31
User entered '10 Mar 2021 09:56:28'	System	10 Mar 2021 15:56:31

US3312395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:34:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 15:07:06

US3312395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:34:02
User entered '24 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 15:07:06

US3312395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:34:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Nov 2020 15:07:06

US3312395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:34:02
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 15:07:06

US3312395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:34:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 15:06:51

US3312395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:04
User entered 'I'	System	24 Nov 2020 15:06:51

US3312395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:22
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 15:06:52

US3312395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:22
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '28 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 15:06:52

US3312395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:22
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 15:06:52

US3312395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:22
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 15:06:52

US3312395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:14:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 15:06:34

US3312395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User entered 'I'	System	29 Dec 2020 15:06:34

US3312395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:34:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 14:14:01

US3312395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:34:51
User entered '25 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 14:14:01

US3312395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:34:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Jan 2021 14:14:01

US3312395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:34:51
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:14:01

US3312395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 21:34:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 14:13:40

US3312395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User entered 'I'	System	26 Jan 2021 14:13:40

US3312395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:51
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	01 Mar 2021 19:58:27
	(b) (4)	

US3312395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:51
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '25 Feb 2021'	Karol Moore (b) (4)	01 Mar 2021 19:58:27
	(b) (4)	

US3312395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:51
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	01 Mar 2021 19:58:27
	(b) (4)	

US3312395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:51
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Mar 2021 19:58:27
	(b) (4)	

US3312395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:15:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	01 Mar 2021 19:58:16
	(b) (4)	

US3312395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:57:38
User entered 'I'	System	01 Mar 2021 19:58:16

US3312395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:16

US3312395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:16

US3312395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:16

US3312395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 19:34:16

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '11:04'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:04'	System	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
	(b) (4)	
User entered '98.0' F	(b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '119'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:34:45

US3312395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:50

US3312395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:34:50

US3312395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:35:02

US3312395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:35:02

US3312395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:51
User entered '12:41'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:35:02

US3312395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:41'	System	30 Mar 2021 19:35:02

US3312395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:35:04

US3312395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 19:35:04

US3312395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:55:14

US3312395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:55:14

US3312395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:55:14

US3312395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:55:14

US3312395

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:55:43

US3312395

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 12:55:43

US3312395

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:46:44
	(b) (4)	

US3312395

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:46:44
	(b) (4)	

US3312395

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[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 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:29
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Clinic (Clinic)'	Karol Moore (b) (4)	06 Mar 2021 18:46:44
	(b) (4)	

US3312395

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'UNBLND_DECIDE'	System	06 Mar 2021 18:46:44

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '03 Mar 2021'	(b) (4)	06 Mar 2021 18:47:06
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[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 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Mar 2021 18:47:06
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:47:06
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Placebo (Placebo)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Placebo (Placebo)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Placebo (Placebo)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:01:43
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:47:06
	(b) (4)	

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'I'	System	06 Mar 2021 18:47:06

US3312395

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'I'	System	06 Mar 2021 18:47:06

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered empty.	System	06 Mar 2021 18:49:25
DataPoint set to visible.	System	06 Mar 2021 18:47:06

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered empty.	System	06 Mar 2021 18:49:25
DataPoint set to visible.	System	06 Mar 2021 18:47:06

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '10:10'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '03 Mar 2021 10:10'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '98.2' F	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Oral (Oral)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '86'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'bpm'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '16'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'breaths/min'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '113'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'mmHg'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '80'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'mmHg'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered missing code ND - Not Done.	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered empty.	System	06 Mar 2021 18:49:25
DataPoint set to visible.	System	06 Mar 2021 18:47:06

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '11:02'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '03 Mar 2021 11:02'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Mar 2021 18:49:32
User entered '98.1' F reason for change: Data Entry Error	Karol Moore (b) (4)	06 Mar 2021 18:49:32
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Mar 2021 18:49:25
User entered '98.1' (non-conformant).	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Oral (Oral)'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '94'	Karol Moore (b) (4)	06 Mar 2021 18:49:25
	(b) (4)	

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'bpm'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '16'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'breaths/min'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '136'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'mmHg'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:01
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '82'	Karol Moore (b) (4)	06 Mar 2021 18:49:25

US3312395

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'mmHg'	System	06 Mar 2021 18:49:25

US3312395

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:15
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:49:39
	(b) (4)	

US3312395

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:15
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:49:39
	(b) (4)	

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Mar 2021 18:50:51
	(b) (4)	

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

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)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	Karol Moore (b) (4)	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'mRNA-1273'	System	06 Mar 2021 18:50:51
DataPoint set to visible.	System	06 Mar 2021 18:47:06

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '10:31'	Karol Moore (b) (4)	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '03 Mar 2021 10:31'	System	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Left Arm (LEFT ARM)'	Karol Moore (b) (4)	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:05:56
User entered 'ONCE'	System	06 Mar 2021 18:50:51

US3312395

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered 'INTRAMUSCULAR'	System	06 Mar 2021 18:50:51

US3312395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:45
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:47:17

US3312395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:45
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:47:17
	(b) (4)	

US3312395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:45
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '09:24'	Karol Moore (b) (4)	06 Mar 2021 18:47:17
	(b) (4)	

US3312395

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '03 Mar 2021 09:24'	System	06 Mar 2021 18:47:17

US3312395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:53
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:47:28

US3312395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:53
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '03 Mar 2021'	Karol Moore (b) (4)	06 Mar 2021 18:47:28

US3312395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:06:53
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '09:23'	Karol Moore (b) (4)	06 Mar 2021 18:47:28
	(b) (4)	

US3312395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:36

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '03 Mar 2021 09:23'	System	06 Mar 2021 18:47:28

US3312395

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

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:07:09
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Mar 2021 18:47:34
	(b) (4)	

US3312395

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

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:12:04
User entered '1'	System	06 Mar 2021 18:47:34

US3312395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:00
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:02

US3312395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:00
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:02

US3312395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:00
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:02

US3312395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:00
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 17:43:02

US3312395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:18:12
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:05

US3312395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
User entered '1'	System	12 Mar 2021 17:43:05

US3312395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:17
User entered 'I'	System	12 Mar 2021 17:43:05
DataPoint set to visible.	System	12 Mar 2021 17:43:05

US3312395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:13

US3312395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:13

US3312395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:13

US3312395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	30 Mar 2021 17:02:13

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '11:04'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:04'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '98.0' F	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '119'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	30 Mar 2021 19:37:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:37:33
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	30 Mar 2021 19:37:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '12:29'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:29'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered '97.6' F	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '85'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '118'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '88'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:37:25

US3312395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:38

US3312395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:37:38

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	30 Mar 2021 17:02:29
DataPoint set to visible.	System	12 Mar 2021 17:43:05

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '11:58'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:58'	System	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 17:02:29

US3312395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:02:34

US3312395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 17:02:34

US3312395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:21:53

US3312395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:22:23
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:21:53

US3312395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:22:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:21:53

US3312395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:21:53

US3312395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:21:57

US3312395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 19:21:57

US3312395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:45:18

US3312395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:45:18

US3312395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:45:18

US3312395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Apr 2021 12:45:18

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '12:24'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 12:24'	System	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '75'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '123'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '81'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Apr 2021 12:46:44

US3312395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:54

US3312395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:46:54

US3312395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:47:23

US3312395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:47:23

US3312395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
User entered '12:52'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:47:23

US3312395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 12:52'	System	29 Apr 2021 12:47:23

US3312395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:01:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:58:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:43
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:59:35
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:19:14

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Cervicalgia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:05:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:05:32
Data point term sent to Coder	System	28 Oct 2020 20:26:21
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	28 Oct 2020 20:25:58
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'UPDATED ' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:25:58
User entered 'CERVICALGIA' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:25:51
User closed query 'Per DM CLR: This AE was noted as a result of a procedure of Manual Vacuum Aspiration. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:24:17
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	26 Oct 2020 18:24:24
Data point term sent to Coder	System	23 Oct 2020 21:11:55

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: This AE was noted as a result of a procedure of Manual Vacuum Aspiration. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' answered with 'REVIEWED AND CORRECTED' (Site from DM). Coding entries removed.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 21:11:31
	Karol Moore (b) (4) (b) (4)	23 Oct 2020 21:11:21
User entered 'CERVICALGIA SECONDARY TO MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Oct 2020 21:11:21
User opened query 'Per DM CLR: This AE was noted as a result of a procedure of Manual Vacuum Aspiration. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:47:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Cervicalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:18:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:18:48
Data point term sent to Coder	System	23 Sep 2020 19:20:16
User entered 'cervicalgia secondary to manual vacuum aspiration'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '12 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 02:38:37
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'still ongoing as of 24nov2020.' (Site from DM).	Karol Moore (b) (4) (b) (4)	30 Nov 2020 22:57:41
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:56:28
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Sep 2020 19:20:12
	(b) (4)	

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Karol Moore (b) (4)	23 Sep 2020 19:20:12
	(b) (4)	

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'I'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:20:12

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:08
User entered 'USA-US300-2021-mRNA-1273-P301000016'	System	18 Feb 2021 18:55:02
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 18:55:02

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Mood alterations with manic symptoms, PT: Mania, LLT: Manic episode - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:59:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:59:05
Data point term sent to Coder	System	17 Feb 2021 18:53:16
User entered 'manic episode'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:53:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:56:31
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.' answered with 'UPdated with resolution per PI' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 21:00:29
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:53:59
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)	15 Mar 2021 12:49:26
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	17 Feb 2021 18:55:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Feb 2021 18:52:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 18:55:03
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		17 Feb 2021 18:55:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 18:55:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	17 Feb 2021 18:52:53
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:49:05
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 15:55:01
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:47:03
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:17:52
Query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 15:54:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 15:53:23
User opened query 'PV Query: As the last dose of study drug was given on 28 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:45:30
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:54:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:54:46
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 18:54:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:52:53
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
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) (4), (b) (6)	08 Mar 2021 16:17:45
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)	08 Mar 2021 16:17:43
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 'CM updated' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 15:54:33
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 'Subject was not compliant with medications, CM updated and correct' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 15:54:25

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	26 Feb 2021 15:46:30
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)	26 Feb 2021 15:46:21
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:56:41
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' answered with 'Resolved per PI' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 21:00:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:53:59
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:49:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	06 Apr 2021 02:03:10

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '55 YEAR OLD MAN WHO ON 01FEB2021 WHILE AT SITE FOR UNBLINDING VISIT, EXHIBITED STRANGE BEHAVIOR SUCH AS SPEAKING IN LOUD NONSENSICAL OUTBURSTS TO STRANGERS WHILE STANDING IN HALLWAY. SUBJECT'S ROOMMATE WHO IS ALSO SUBJECT'S EMERGENCY CONTACT WAS PRESENT AND REPORTED THAT SUBJECT HAS HISTORY OF SIMILAR BEHAVIOR IN PAST DUE TO BIPOLAR DISORDER (NOT REVEALED AT SCREENING) WHEN NON-COMPLIANT WITH MEDICATION. SUBJECT AND ROOMMATE WERE ADVISED THAT SUBJECT COULD NOT BE DOSED WHEN UNSTABLE AND ROOMMATE AGREED TO TAKE SUBJECT TO ER OR TO SUBJECT'S PROVIDER FOR EVALUATION AND RE-INITIATION OF THERAPY. SUBJECT AND ROOMMATE CALLED TODAY, 17FEB2021 TO REPORT THAT SUBJECT WAS HOSPITALIZED FROM APPROXIMATELY 02FEB2021 THROUGH 15FEB2021 FOR BIPOLAR EPISODE WITH PSYCHOTIC FEATURES BUT THAT HE IS STABLE NOW. MED RECORDS WILL BE PROCURED AND REVIEWED AND CONTACT OR VISIT WITH SUBJECT WILL BE PLANNED TO DECIDE HOW TO PROCEED IN STUDY. Update 03/05/21:Med records reviewed confirming subject's past history of Bipolar Disorder and current episode of mania due to medication non-compliance and recent social stressors. Subject also has history of neuroleptic parkinsonism possibly complicating the compliance issue. Subject was admitted from 02Feb thru 15Feb and treated with depakote, olanzapine, and zolpidem showing steady improvement through discharge. Subject was seen at site 03Mar; he was stable and was dosed without complications. Med HX and CM updated, SAE Closed per PI' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 21:00:07

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was reported subject was in for unblinding visit. Please confirm if the subject was in fact unblinded. If so, please complete the unblinding form' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:17:41
User closed query 'PV Query: It was reported the subject has a history of bipolar disorder. Please consider updating the subject's past medical history to include this.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:17:37
Query 'PV Query: It was reported the subject has a history of bipolar disorder. Please consider updating the subject's past medical history to include this.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 15:53:47
Query 'PV Query: It was reported subject was in for unblinding visit. Please confirm if the subject was in fact unblinded. If so, please complete the unblinding form' answered with 'unblinding decision visit did not occur at that time' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 15:53:43
User opened query 'PV Query: It was reported the subject has a history of bipolar disorder. Please consider updating the subject's past medical history to include this.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:46:09
User opened query 'PV Query: It was reported subject was in for unblinding visit. Please confirm if the subject was in fact unblinded. If so, please complete the unblinding form' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:45:49

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '55 year old man who on 01Feb2021 while at site for unblinding visit, exhibited strange behavior such as speaking in loud nonsensical outbursts to strangers while standing in hallway. Subject's roommate who is also subject's emergency contact was present and reported that subject has history of similar behavior in past due to Bipolar disorder (not revealed at screening) when non-compliant with medication. Subject and roommate were advised that subject could not be dosed when unstable and roommate agreed to take subject to ER or to subject's provider for evaluation and re-initiation of therapy. Subject and roommate called today, 17Feb2021 to report that subject was hospitalized from approximately 02Feb2021 through 15Feb2021 for Bipolar episode with psychotic features but that he is stable now. Med records will be procured and reviewed and contact or visit with subject will be planned to decide how to proceed in study'	(b) (4), (b) (6)	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 18:52:53

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 19:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 19:41:04
Data point term sent to Coder	System	30 Mar 2021 19:39:57
User entered 'Nasal congestion'	(b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
User entered empty.	System	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
User entered empty.	System	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:12:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:07:57
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
User entered '0'	System	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57
User entered '0'	System	30 Mar 2021 19:39:42

US3312395

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:45:57

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:01:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:58:41
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:52:52
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 19:12:05
User entered 'No (N)'	Karol Moore (b) (4)	11 Sep 2020 22:48:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 22:50:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 22:50:42
Data point term sent to Coder	System	23 Sep 2020 19:15:02
User entered 'cyclobenzaprine'	Karol Moore (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '10'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'three times daily (TID)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:19
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Sep 2020 19:14:02
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:19
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:14:02
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 19:14:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:09:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:09:35
Data point term sent to Coder	System	18 Oct 2020 00:22:14
User closed query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' (Site from System).	System	18 Oct 2020 00:21:46
Query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' answered with 'updated per source' (Site from System).	Karol Moore (b) (4)	18 Oct 2020 00:21:46
User entered 'NAPROXEN' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 00:21:37
User opened query 'DM-Coding: For coding purposes please provide the medication used for the reported event or move this term to an appropriate procedure field as it cannot be referenced as a drug/medication.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 21:32:33
Data point term sent to Coder	System	23 Sep 2020 19:15:02
User entered 'cervicalgia'	Karol Moore (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'CERVICALGIA' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 00:21:37
User entered 'naproxen'	(b) (4)	
	Karol Moore (b) (4)	23 Sep 2020 19:14:23
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '250'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:30
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Sep 2020 19:14:23
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:30
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:14:23
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 19:14:23

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 10:23:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Oct 2020 10:23:34
Data point term sent to Coder Coding entries removed.	System	23 Oct 2020 21:08:52
	Karol Moore (b) (4)	23 Oct 2020 21:08:44
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 04:45:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 04:45:52
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 19:15:03
User entered 'toradol'	Karol Moore (b) (4)	23 Sep 2020 19:15:02
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:15:02
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
reason for change: Data Entry Error	Karol Moore (b) (4)	23 Oct 2020 21:08:44
User entered 'Other (OTHER)'	(b) (4)	
	Karol Moore (b) (4)	23 Sep 2020 19:15:02
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and specify the type of INJECTION (e.g. IM, IV etc.) as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:23:45
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and specify the type of INJECTION (e.g. IM, IV etc.) as appropriate. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Oct 2020 21:08:52
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Oct 2020 21:08:44
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and specify the type of INJECTION (e.g. IM, IV etc.) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:32:26
User entered 'injection'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:15:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'CONFIRMED. THIS MEDICATION DOES NOT MEET EXCLUSION CRITERIA 12 PER PI' (Site from DM).	(b) (4) (b) (4), (b) (6) Karol Moore (b) (4) (b) (4)	19 Nov 2020 10:37:41 17 Nov 2020 21:06:34
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:51:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:04:00

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:25:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:25:39
Data point term sent to Coder	System	23 Sep 2020 19:17:07
User entered 'methylpredisolone'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '20'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:54
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Sep 2020 19:16:06
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Oct 2020 00:26:54
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 19:16:06
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 19:16:06

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:16
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:39
Data point term sent to Coder	System	23 Sep 2020 19:17:07
User entered 'methylpredisolone'	Karol Moore (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:18:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:18:49
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 19:18:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:16:33
User entered empty.	System	23 Sep 2020 19:16:33
	Karol Moore (b) (4)	23 Sep 2020 19:16:33
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '20'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:16:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '15 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '15 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:16:33

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
Data point term sent to Coder	System	23 Sep 2020 19:17:10
User entered 'methylpredisolone'	Karol Moore (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:17:02
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:17:02
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '16 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '16 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
Data point term sent to Coder	System	23 Sep 2020 19:18:11
User entered 'methylpredisolone'	Karol Moore (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:17:27
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:17:27
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:17:27

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:00
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
Data point term sent to Coder	System	23 Sep 2020 19:18:11
User entered 'methylpredisolone'	Karol Moore (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:18:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:18:36
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 19:18:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:18:02
User entered empty.	System	23 Sep 2020 19:18:02
	Karol Moore (b) (4)	23 Sep 2020 19:18:02
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '8'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '18 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '18 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:02

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:01
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 00:25:40
Data point term sent to Coder	System	23 Sep 2020 19:19:14
User entered 'methylpredisolone'	Karol Moore (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:18:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 19:18:31
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 19:18:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 19:18:25
User entered empty.	System	23 Sep 2020 19:18:25
	Karol Moore (b) (4)	23 Sep 2020 19:18:25
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'cervicalgia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '4'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:18:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:18:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	23 Sep 2020 19:18:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '19 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '19 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 19:18:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:08:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:08:08
Data point term sent to Coder	System	06 Mar 2021 15:56:57
User entered 'depakote'	(b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'bipolar/manic episode'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '500'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:48:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:48:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:48:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:48:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:48:46
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:48:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Mar 2021 15:56:25

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	06 Mar 2021 15:59:01
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	06 Mar 2021 15:59:01
Data point term sent to Coders	System	06 Mar 2021 15:57:57
User entered 'zyprexa'	(b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'bipolar/manic episode'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '20'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:48:56
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:48:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:48:56
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:48:56
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:48:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Mar 2021 15:57:03

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 06:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 06:54:44
Data point term sent to Coder	System	06 Mar 2021 15:58:58
User entered 'zolpidem'	(b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'bipolar/manic episode'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '10'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'HS'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:49:05
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:49:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:49:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 12:49:05
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:49:05
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:49:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:53:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 15:58:30

US3312395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:01:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:52:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:56:54

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'USA-US300-2021-MRNA-1273-P301000016'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Carlos'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Fierro'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '16300 College Blvd'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Shawnee'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'KS'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '66219'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:18:50
User entered 'US'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 12:57:08
User entered '2'	System	08 Mar 2021 16:19:49
User entered '1'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'USA-US300-2021-MRNA-1273-P301000016'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Carlos'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Fierro'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '16300 College Blvd'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Shawnee'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'KS'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '66219'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:18:50
User entered 'US'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 12:57:08
User entered '2'	System	08 Mar 2021 16:19:49
User entered '1'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:01:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '18/Feb/2021 12:55'	(b) (4) System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:01:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:18:50
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'USA-US300-2021-MRNA-1273-P301000016'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Carlos'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Fierro'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '16300 College Blvd'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Shawnee'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'KS'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '66219'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:18:50
User entered 'US'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 12:57:08
User entered '2'	System	08 Mar 2021 16:19:49
User entered '1'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:01:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '08/Mar/2021 11:19'	(b) (4) System	08 Mar 2021 16:19:49

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:01:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:19:49

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'USA-US300-2021-MRNA-1273-P301000016'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Yes (Y)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'No (N)'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Carlos'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Fierro'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '16300 College Blvd'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'Shawnee'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered 'KS'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:55:24
User entered '66219'	System	18 Feb 2021 18:55:02

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:18:50
User entered 'US'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 12:57:08
User entered '2'	System	08 Mar 2021 16:19:49
User entered '1'	System	18 Feb 2021 18:55:31

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:01:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered '18/Mar/2021 08:57'	(b) (4) System	18 Mar 2021 12:57:08

US3312395

Folder: SAE USA-US300-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:01:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:03:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:57:08