

US3202310 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:46:38

All time stamps listed in this document are displayed in GMT

US3202310

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

[Participant ID](#)

US3202310

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

US3202310

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

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

Visit date (dd MMM yyyy)	25 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
------------	------

US3202310

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input checked="" type="radio"/> Male <input 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

US3202310

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	25 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

US3202310

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3202310

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Were any significant conditions reported?

Yes ☒

No ☐

US3202310

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3202310

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	TOTAL VAGINAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3202310

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	TYPE 2 DIABETES MELLITUS
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3202310

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	ALCOHOL INTAKE- 4 DRINKS PER WEEK
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3202310

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	GASTRITIS
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3202310

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

US3202310

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	BENIGN UTERINE FIBROID TUMORS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3202310

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Condition	IRON-DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202310

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:17
Height (xxx.x)	170 cm
Weight (xxx.x)	86 kg
BMI (xxx.x)	29.75779 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202310

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3202310

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1999

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3202310

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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

Visit date (dd MMM yyyy)	25 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
------------	--------

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 107971

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 ☒

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Height	ND - Not Done
Weight	ND - Not Done

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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)	25 AUG 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:17
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:44
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3202310

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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.

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 10:09

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3202310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

09:33 (24 HR)

Collection date and time (derived)

25 AUG 2020 09:33

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:31	25 AUG 2020 09:31
Nasopharyngeal Swab 2	No		

US3202310

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 10:35

PC Open Date & Time

25 AUG 2020 10:29

PC Close Date & Time

25 AUG 2020 12:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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 98.0 °F

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

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

PC Time Stamp	25 AUG 2020 14:11
PC Open Date & Time	25 AUG 2020 13:54
PC Close Date & Time	26 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

97.4 °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

26 AUG 2020 13:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

27 AUG 2020 14:51

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 15:11

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

97.8 °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

29 AUG 2020 15:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 16:20

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

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

31 AUG 2020 16:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

25 AUG 2020 10:36

PC Open Date & Time

25 AUG 2020 10:29

PC Close Date & Time

25 AUG 2020 12:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

25 AUG 2020 14:11

PC Open Date & Time

25 AUG 2020 13:54

PC Close Date & Time

26 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

27 AUG 2020 14:51

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

28 AUG 2020 15:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

29 AUG 2020 15:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

30 AUG 2020 16:21

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

31 AUG 2020 16:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:36
PC Open Date & Time	25 AUG 2020 10:29
PC Close Date & Time	25 AUG 2020 12:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 14:12
PC Open Date & Time	25 AUG 2020 13:54
PC Close Date & Time	26 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

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 ☒

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 13:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

52 of 1875

EAB) (1725)

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:52
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

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)

54 of 1875

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 15:11
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

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 ☒

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 1875

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:21
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

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 ☒

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 16:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3202310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 SEP 2020

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

Comments NO ANSWER

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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)	23 SEP 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:16
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:03
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3202310

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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.

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 11:20

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3202310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

10:53 (24 HR)

Collection date and time (derived)

23 SEP 2020 10:53

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	23 SEP 2020 10:50
Nasopharyngeal Swab 2	No		

US3202310

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 11:42

PC Open Date & Time

23 SEP 2020 11:40

PC Close Date & Time

23 SEP 2020 14:10

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.7 °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	23 SEP 2020 16:24
PC Open Date & Time	23 SEP 2020 15:05
PC Close Date & Time	24 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 13:55

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 13:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

26 SEP 2020 19:12

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

94.5 °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

27 SEP 2020 15:30

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

28 SEP 2020 14:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

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

29 SEP 2020 14:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

23 SEP 2020 11:43

PC Open Date & Time

23 SEP 2020 11:40

PC Close Date & Time

23 SEP 2020 14:10

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

23 SEP 2020 16:25

PC Open Date & Time

23 SEP 2020 15:05

PC Close Date & Time

24 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

24 SEP 2020 13:56

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

25 SEP 2020 13:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

26 SEP 2020 19:12

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

27 SEP 2020 15:31

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

28 SEP 2020 14:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

29 SEP 2020 14:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 11:43
PC Open Date & Time	23 SEP 2020 11:40
PC Close Date & Time	23 SEP 2020 14:10

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 16:25
PC Open Date & Time	23 SEP 2020 15:05
PC Close Date & Time	24 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

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 ☒

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:56
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

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 ☒

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 13:58
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

100 of 1875

EAB) (1725)

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:13
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

102 of 1875

EAB) (1725)

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 15:31
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

104 of 1875

EAB) (1725)

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

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)

106 of 1875

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 14:53
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3202310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:02

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 12:51:17

Generated On: 09 Jun 2021 15:46:38

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3202310

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3202310

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

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.

US3202310

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3202310

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:21:03

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 OCT 2020 12:09:14
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 14:33:37

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 10:19:30

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

22 NOV 2020 07:53:58

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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	27 NOV 2020 09:00:10
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

03 DEC 2020 13:11:44

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

10 DEC 2020 11:13:53

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

17 DEC 2020 17:39:03

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 02:23:32

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 00:17:22

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

07 JAN 2021 00:06:20

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 07:56:23

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

21 JAN 2021 00:40:31

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 07:21:09

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 13:25:28

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

11 FEB 2021 07:56:20

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 14:48:06

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 17:36:23

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 07:51:38

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 07:59:49

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

18 MAR 2021 00:04:02

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

25 MAR 2021 02:25:51

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

01 APR 2021 21:29:13

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

08 APR 2021 08:09:33

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

17 APR 2021 12:00:28

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

22 APR 2021 08:12:01

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 APR 2021 15:38:43
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 264

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 271

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 285

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 299

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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="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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 334

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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="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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 425

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

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 <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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 530

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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="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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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="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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 684

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 719

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

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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="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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

DAY 796

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

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

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

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

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

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 ☐

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

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

US3202310

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:46:38

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		04 MAR 2021 07:51:57

US3202310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:51:17

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:51:17

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202310

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:01:06

Generated On: 09 Jun 2021 15:46:38

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

Visit date (dd MMM yyyy)	31 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	VISIT4
------------	--------

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:01:06

Generated On: 09 Jun 2021 15:46:38

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202310

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

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.

US3202310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

10:10 (24 HR)

Collection date and time (derived)

31 MAR 2021 10:10

US3202310

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:01:05

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202310

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202310

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:46:38

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"/>

US3202310

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:46:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202310

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

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

Visit date (dd MMM yyyy)	5 FEB 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3202310

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

Date of updated informed consent (dd MMM yyyy) 6 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 5 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3202310

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 FEB 2021
Collection time (00:00-23:59)	13:30 (24 HR)
Collection date and time (derived)	5 FEB 2021 13:30

US3202310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 FEB 2021
Collection time (00:00 - 23:59)	13:27
Collection Date and Time (derived)	5 FEB 2021 13:27

US3202310

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:15:06

Generated On: 09 Jun 2021 15:46:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

AEID	USA-US128-2020-MRNA-1273-P30 1000005
Adverse event	WORSENING OF HIATAL HERNIA
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)	06 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	24 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	325 of 1875

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

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	True
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	

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

SUBJECT NOTIFIED US THAT
SHE HAD A FLARE UP OF
HIATAL HERNIA AND HAD
HIATAL HERNIA REPAIR
SURGERY ON 23 OCT 2020
WHICH REQUIRED OVERNIGHT
HOSPITALIZATION. SUBJECT
WAS DISCHARGED 24 OCT 2020.

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

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

AEID	
Adverse event	HERPES ZOSTER
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)	28 APR 2021
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 checked="" type="radio"/> Grade 2/Moderate <input 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)

328 of 1875

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

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

Yes ☒

No ☐

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

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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)

331 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication PRILOSEC

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

333 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication MOTRIN (IBUPROFEN)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF HIATAL
HERNIA

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF HIATAL
HERNIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

337 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF HIATAL
HERNIA

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication ANCEF (CEFAZOLIN)

Prophylaxis Yes ☒
No ☐

Indication SURGERY INFECTION
PROPHYLAXIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES ZOSTER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

343 of 1875

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 May 2021 00:53:44

Generated On: 09 Jun 2021 15:46:38

	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)	28 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 OCT 2020	DAVINCI HIATAL HERNIA REPAIR	Adverse Event	

US3202310

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:46:38

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

US3202310

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:46:38

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 ☐

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

SAEID	USA-US128-2020-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

SAEID	USA-US128-2020-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/OCT/2020 10:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

SAEID	USA-US128-2020-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/NOV/2020 09:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 16:01:04

Generated On: 09 Jun 2021 15:46:38

SAEID	USA-US128-2020-MRNA-1273-P301000005
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202310 (Prod: WR-ClinSearch, LLC)

US3202310

Form: Participant Creation

Generated On: 09 Jun 2021 15:46:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:48:31
User entered 'US3202310'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 12:59:23

US3202310

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:33

US3202310

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 12:59:24

US3202310

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:33

US3202310

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'SCRN'	System	25 Aug 2020 13:40:33

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 12:59:25

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '63'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'YEARS'	System	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '63'	System	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:35:11
Query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' answered with 'Field completed' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 14:26:27
User opened query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:04:23
User entered 'Female (F)'	Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 16:59:47

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Aug 2020'	System	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '2020'	System	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Amendment 3 (3)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:46

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 12:59:24

US3202310

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'I'	System	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:46:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:59
Query 'Surgical consult records of 08Oct2020 also = history of Iron Deficiency Anemia with Iron infusions, please verify and update' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:19:56
User opened query 'Surgical consult records of 08Oct2020 also = history of Iron Deficiency Anemia with Iron infusions, please verify and update' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:23:10
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 12:56:00

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 12:57:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 12:57:47
Data point term sent to Coder	System	12 Sep 2020 12:57:09
User entered 'Hypercholesterolemia'	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1980'	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1980'	System	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1980'	System	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 12:56:47

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total vaginal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 13:00:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 13:00:49
Data point term sent to Coder	System	12 Sep 2020 13:00:15
User entered 'Total vaginal hysterectomy'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1999'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1999'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1999'	System	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1999'	System	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1999'	System	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1999'	System	12 Sep 2020 12:59:27

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 10:09:47
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'none listed per subj' (Site from DM).	Teresa Deese (b) (4)	04 Nov 2020 18:45:29
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:15:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:41:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 01:41:00
Data point term sent to Coder	System	22 Sep 2020 01:39:31
Coding entries removed.	Erica Osmundsen (b) (4)	22 Sep 2020 01:39:28
User entered 'Type 2 DIABETES mellitus' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	22 Sep 2020 01:39:28

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:26:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:26:45
Data point term sent to Coder	System	12 Sep 2020 13:03:15
User entered 'History of diabetes type 2- Previously diagnosed in 2015 then subject lost weight and no longer meets criteria. Last A1C- 5.2 in 2019'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Nov 2020 21:32:37
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	04 Nov 2020 18:45:55
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	04 Nov 2020 18:45:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 18:45:41
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	23 Nov 2020 21:32:37
User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:09:49
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	04 Nov 2020 18:46:02
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	04 Nov 2020 18:45:55
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:16:00
User entered 'UN Dec 2017'	Tiffany Jewell (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 2015'	System	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '2015'	System	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 2017'	System	23 Nov 2020 21:32:37
User entered empty.	System	04 Nov 2020 18:45:55
User entered 'Dec 2017'	System	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '2017'	System	23 Nov 2020 21:32:37
User entered empty.	System	04 Nov 2020 18:45:55
User entered '2017'	System	12 Sep 2020 13:02:36

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Social circumstances, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 17:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 17:49:41
Data point term sent to Coder	System	12 Sep 2020 13:05:19
User entered 'Alcohol intake- 4 drinks per week'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'I'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:33

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 13:06:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 13:06:49
Data point term sent to Coder	System	12 Sep 2020 13:05:19
User entered 'Gastritis'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN Mar 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Mar 2020'	System	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '2020'	System	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Sep 2020 13:04:51

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 14:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 14:55:48
Data point term sent to Coder	System	12 Nov 2020 14:55:10
User entered 'HIATAL HERNIA'	Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1993'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1993'	System	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1993'	System	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Nov 2020 14:54:16

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroid - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:13:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:13:53
Data point term sent to Coder	System	12 Nov 2020 15:00:20
User entered 'BENIGN UTERINE FIBROID TUMORS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 15:00:06
Data point term sent to Coder	System	12 Nov 2020 14:56:11
User entered 'GASTRITIS'	Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1999' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:00:06
User entered 'UN Mar 2020'	Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:00:06
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1999' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:00:06
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1999'	System	12 Nov 2020 15:00:06
User entered 'Mar 2020'	System	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1999'	System	12 Nov 2020 15:00:06
User entered '2020'	System	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Jan 1999'	System	12 Nov 2020 15:00:06
User entered empty.	System	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '1999'	System	12 Nov 2020 15:00:06
User entered empty.	System	12 Nov 2020 14:55:34

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:24:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:24:47
Data point term sent to Coder	System	12 Nov 2020 15:09:32
User entered 'IRON-DEFICIENCY ANEMIA'	Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN Mar 2020'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered 'Mar 2020'	System	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered '2020'	System	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User entered empty.	System	12 Nov 2020 15:09:27

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '09:17'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User entered '25 Aug 2020 09:17'	System	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '170' cm	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16
DataPoint set to visible.	(b) (4) System	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '86' kg	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16
DataPoint set to visible.	(b) (4) System	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User entered '29.75779'	System	12 Sep 2020 13:07:16
DataPoint set to visible.	System	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User entered 'kg/m2'	System	12 Sep 2020 13:07:16
DataPoint set to visible.	System	25 Aug 2020 13:40:51

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Dec 2020 09:17:42
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	15 Dec 2020 21:04:31
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4) (b) (4)	15 Dec 2020 21:04:26
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:18:37
User entered 'Other (Other)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
Query ' Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 15:05:51
User opened query ' Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:36:34
User entered 'bpm'	System	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
Query ' Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 15:05:53
User opened query ' Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:36:43
User entered 'breaths/min'	System	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
Query ' Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 15:05:54
User opened query ' Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:37:10
User entered 'mmHg'	System	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44
Query ' Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 15:05:56
User opened query ' Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:37:34
User entered 'mmHg'	System	12 Sep 2020 13:07:16

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44

US3202310

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:44

US3202310

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:07:28

US3202310

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:07:28

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:42
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'TOTAL VAGINAL HYSTERECTOMY WAS TERM LISTED IN MH AND I HAVE UPDATED EDC PER SOURCE TO INCLUDE THE ASSOCIATED CONDITION-BENIGN UTERINE FIBROID TUMORS' (Site from DM).	Erica Osmundsen (b) (4)	12 Nov 2020 15:00:54
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:39:04
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'UN UNK 1999'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:46:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:04

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'I'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'I'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:27:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:08:53

US3202310

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:02

US3202310

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:02

US3202310

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:41:02

US3202310

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'VISIT1'	System	25 Aug 2020 13:41:02

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:34:43

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '107971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:34:43

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per protocol history of DM would = at risk. Protocol Deviation captured. please verify documentation in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:58:20
Query 'Per protocol history of DM would = at risk. Protocol Deviation captured. please verify documentation in source.' answered with 'DIABETES DIAGNOSIS HAD RESOLVED AT TIME OF RANDOMIZATION FOR STUDY, BUT STILL HAD HISTORY OF THIS CONDITION SO STRATIFICATION ERROR' (Site from CRA).	Erica Osmundsen (b) (4)	23 Nov 2020 21:31:26
User opened query 'Per protocol history of DM would = at risk. Protocol Deviation captured. please verify documentation in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 20:57:24
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:34:43

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:22:17
Query ' PER CDM: Please complete this section of the form' answered with 'fields fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	03 Sep 2020 22:55:43
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Sep 2020 22:55:40
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:50:08

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 22:55:40

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 22:55:40

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	24 Nov 2020 14:40:55
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:40:55
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 13:58:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:58:30
User closed query 'As per protocol history of Diabetes would = at risk. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:58:28
Query 'As per protocol history of Diabetes would = at risk. Please verify and update.' answered with 'DIABETES DIAGNOSIS HAD RESOLVED AT TIME OF RANDOMIZATION FOR STUDY, BUT STILL HAD HISTORY OF THIS CONDITION SO STRATIFICATION ERROR' (Site from CRA).	Erica Osmundsen (b) (4)	23 Nov 2020 21:31:21
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	23 Nov 2020 21:31:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Nov 2020 21:31:17
User opened query 'As per protocol history of Diabetes would = at risk. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 20:56:30
User closed query 'per medical history subject does have history, please verify and submit an e-PIP to confirm stratification error' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 20:56:30
Query 'per medical history subject does have history, please verify and submit an e-PIP to confirm stratification error' answered with 'ePIP submitted--no current diagnosis of diabetes' (Site from CRA).	Erica Osmundsen (b) (4)	15 Oct 2020 15:38:11

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User opened query 'per medical history subject does have history, please verify and submit an e-PIP to confirm stratification error' (Site from CRA). User entered 'No (N)'	(b) (4), (b) (6) zackery harmon (b) (4) (b) (4)	15 Oct 2020 13:21:14 03 Sep 2020 22:55:40

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 22:55:40
	(b) (4)	

US3202310

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:39:07
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 02:47:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:47:47

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '09:17'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered '25 Aug 2020 09:17'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '36.2' C	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '71'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'bpm'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '16'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'breaths/min'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:43:34
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 13:43:30
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'NCS' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:42:50
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:01:03
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:22:17
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'B/P check 144/90' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:12:46
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Sep 2020 13:12:06
User entered '162'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'mmHg'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '90'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'mmHg'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '10:44'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered '25 Aug 2020 10:44'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '36.6' C	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '90'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'bpm'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '16'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'breaths/min'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:33:11
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 14:33:08
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form ' answered with 'NCS' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:42:58
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:01:22
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:22:17
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per subject- they get anxious at doctors office and B/P is usually 120/80's. Ok per sub PI.' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:15:20
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Sep 2020 13:12:06
User entered '158'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'mmHg'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '90'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'mmHg'	System	12 Sep 2020 13:12:06

US3202310

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:15:29

US3202310

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:15:29

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '10:09'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered '25 Aug 2020 10:09'	System	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4)	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'ONCE'	System	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 14:12:38

US3202310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:18

US3202310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:18

US3202310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '09:33'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:18

US3202310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered '25 Aug 2020 09:33'	System	25 Aug 2020 13:41:18

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '25 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '09:31'	Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered '25 Aug 2020 09:31'	System	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered empty.	System	25 Aug 2020 13:41:30

US3202310

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	25 Aug 2020 13:41:35

US3202310

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'I'	System	25 Aug 2020 13:41:35

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:34:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '25b8d46d-abd8-439c-8452-4f479c34f892'	System	25 Aug 2020 14:35:15
User entered 'Yes (Y)'	System	25 Aug 2020 14:35:15

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:34:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '25b8d46d-abd8-439c-8452-4f479c34f892' User entered '97.4'	System	25 Aug 2020 14:35:15
	System	25 Aug 2020 14:35:15

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:34:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '25b8d46d-abd8-439c-8452-4f479c34f892'	System	25 Aug 2020 14:35:15
User entered 'No (N)'	System	25 Aug 2020 14:35:15

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:35:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '25b8d46d-abd8-439c-8452-4f479c34f892'	System	25 Aug 2020 14:35:15
User entered '25 Aug 2020 10:35'	System	25 Aug 2020 14:35:15

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 10:29'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 12:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6905c35a-0a08-4b9c-b17c-fa0149cf32a0' User entered 'Yes (Y)'	System	25 Aug 2020 18:11:35
	System	25 Aug 2020 18:11:35

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6905c35a-0a08-4b9c-b17c-fa0149cf32a0' User entered '98.0'	System	25 Aug 2020 18:11:35
	System	25 Aug 2020 18:11:35

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:27', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6905c35a-0a08-4b9c-b17c-fa0149cf32a0'	System	25 Aug 2020 18:11:35
User entered 'No (N)'	System	25 Aug 2020 18:11:35

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6905c35a-0a08-4b9c-b17c-fa0149cf32a0' User entered '25 Aug 2020 14:11'	System	25 Aug 2020 18:11:35
	System	25 Aug 2020 18:11:35

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 13:54'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 2'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T12:52:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7c9e58a9-887f-49ce-9e91-3244177d8493'	System	26 Aug 2020 17:02:36
User entered 'Yes (Y)'	System	26 Aug 2020 17:02:36

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T12:52:11', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7c9e58a9-887f-49ce-9e91-3244177d8493' User entered '97.4'	System	26 Aug 2020 17:02:36
	System	26 Aug 2020 17:02:36

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7c9e58a9-887f-49ce-9e91-3244177d8493'	System	26 Aug 2020 17:02:36
User entered 'No (N)'	System	26 Aug 2020 17:02:36

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7c9e58a9-887f-49ce-9e91-3244177d8493'	System	26 Aug 2020 17:02:36
User entered '26 Aug 2020 13:02'	System	26 Aug 2020 17:02:36

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 3'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd136de40-357d-4519-a0ab-2d89a85ad8f9' User entered 'Yes (Y)'	System	27 Aug 2020 18:51:32
	System	27 Aug 2020 18:51:32

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:21', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd136de40-357d-4519-a0ab-2d89a85ad8f9' User entered '96.8'	System	27 Aug 2020 18:51:32
	System	27 Aug 2020 18:51:32

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd136de40-357d-4519-a0ab-2d89a85ad8f9'	System	27 Aug 2020 18:51:32
User entered 'No (N)'	System	27 Aug 2020 18:51:32

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:29', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd136de40-357d-4519-a0ab-2d89a85ad8f9' User entered '27 Aug 2020 14:51'	System	27 Aug 2020 18:51:32
	System	27 Aug 2020 18:51:32

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 4'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '64de8c51-50f7-43ee-84c7-290720d5bed6' User entered 'Yes (Y)'	System	28 Aug 2020 19:11:13
	System	28 Aug 2020 19:11:13

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:01', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '64de8c51-50f7-43ee-84c7-290720d5bed6' User entered '98.2'	System	28 Aug 2020 19:11:13
	System	28 Aug 2020 19:11:13

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '64de8c51-50f7-43ee-84c7-290720d5bed6' User entered 'No (N)'	System	28 Aug 2020 19:11:13
	System	28 Aug 2020 19:11:13

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '64de8c51-50f7-43ee-84c7-290720d5bed6' User entered '28 Aug 2020 15:11'	System	28 Aug 2020 19:11:13
	System	28 Aug 2020 19:11:13

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 5'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:03:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2600c23e-ae01-48f2-8e7b-91b7c54767ab' User entered 'Yes (Y)'	System	29 Aug 2020 19:04:16
	System	29 Aug 2020 19:04:16

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:04', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2600c23e-ae01-48f2-8e7b-91b7c54767ab' User entered '97.8'	System	29 Aug 2020 19:04:16
	System	29 Aug 2020 19:04:16

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:08', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2600c23e-ae01-48f2-8e7b-91b7c54767ab'	System	29 Aug 2020 19:04:16
User entered 'No (N)'	System	29 Aug 2020 19:04:16

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2600c23e-ae01-48f2-8e7b-91b7c54767ab' User entered '29 Aug 2020 15:04'	System	29 Aug 2020 19:04:16
	System	29 Aug 2020 19:04:16

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 6'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b572f72d-f236-4aa4-86d2-04c4f966e04a' User entered 'Yes (Y)'	System	30 Aug 2020 20:20:53
	System	30 Aug 2020 20:20:53

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b572f72d-f236-4aa4-86d2-04c4f966e04a' User entered '98.2'	System	30 Aug 2020 20:20:53
	System	30 Aug 2020 20:20:53

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:47', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b572f72d-f236-4aa4-86d2-04c4f966e04a'	System	30 Aug 2020 20:20:53
User entered 'No (N)'	System	30 Aug 2020 20:20:53

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b572f72d-f236-4aa4-86d2-04c4f966e04a'	System	30 Aug 2020 20:20:53
User entered '30 Aug 2020 16:20'	System	30 Aug 2020 20:20:53

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 7'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7cc91a0a-d3a2-4ecb-9833-56fcabec552b' User entered 'Yes (Y)'	System	31 Aug 2020 20:46:51
	System	31 Aug 2020 20:46:51

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7cc91a0a-d3a2-4ecb-9833-56fcabec552b' User entered '97.6'	System	31 Aug 2020 20:46:51
	System	31 Aug 2020 20:46:51

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7cc91a0a-d3a2-4ecb-9833-56fcabec552b'	System	31 Aug 2020 20:46:51
User entered 'No (N)'	System	31 Aug 2020 20:46:51

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7cc91a0a-d3a2-4ecb-9833-56fcabec552b' User entered '31 Aug 2020 16:39'	System	31 Aug 2020 20:46:51
	System	31 Aug 2020 20:46:51

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:35:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '57acc07d-701a-442b-abdb-a1a39643bc43'	System	25 Aug 2020 14:36:10
User entered 'None (1)'	System	25 Aug 2020 14:36:10

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:35:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '57acc07d-701a-442b-abdb-a1a39643bc43' User entered 'No (N)'	System	25 Aug 2020 14:36:10
	System	25 Aug 2020 14:36:10

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:35:48', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '57acc07d-701a-442b-abdb-a1a39643bc43'	System	25 Aug 2020 14:36:10
User entered 'No (N)'	System	25 Aug 2020 14:36:10

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:35:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '57acc07d-701a-442b-abdb-a1a39643bc43' User entered 'None (1)'	System	25 Aug 2020 14:36:10
	System	25 Aug 2020 14:36:10

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:04', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '57acc07d-701a-442b-abdb-a1a39643bc43' User entered '25 Aug 2020 10:36'	System	25 Aug 2020 14:36:10
	System	25 Aug 2020 14:36:10

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 10:29'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 12:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '199d544e-d2cd-4099-8d5e-abc11433db9f' User entered 'None (1)'	System	25 Aug 2020 18:11:54
	System	25 Aug 2020 18:11:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:41', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '199d544e-d2cd-4099-8d5e-abc11433db9f' User entered 'No (N)'	System	25 Aug 2020 18:11:54
	System	25 Aug 2020 18:11:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '199d544e-d2cd-4099-8d5e-abc11433db9f' User entered 'No (N)'	System	25 Aug 2020 18:11:54
	System	25 Aug 2020 18:11:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:48', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '199d544e-d2cd-4099-8d5e-abc11433db9f' User entered 'None (1)'	System	25 Aug 2020 18:11:54
	System	25 Aug 2020 18:11:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:52', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '199d544e-d2cd-4099-8d5e-abc11433db9f' User entered '25 Aug 2020 14:11'	System	25 Aug 2020 18:11:54
	System	25 Aug 2020 18:11:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 13:54'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 2'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:01:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d'	System	26 Aug 2020 17:02:21
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:01:10', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d' User entered 'No (N)'	System	26 Aug 2020 17:02:21
	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:01:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d' User entered 'Yes (Y)'	System	26 Aug 2020 17:02:21
	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:01:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d' User entered '2'	System	26 Aug 2020 17:02:21
	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d' User entered 'None (1)'	System	26 Aug 2020 17:02:21
	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:16', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '355862be-a0ad-452a-9c48-1bf8bd889e0d' User entered '26 Aug 2020 13:02'	System	26 Aug 2020 17:02:21
	System	26 Aug 2020 17:02:21

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 3'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'acc60ec0-17f0-4ff2-85de-1acee0170e7a' User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 18:51:59
	System	27 Aug 2020 18:51:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'acc60ec0-17f0-4ff2-85de-1acee0170e7a' User entered 'No (N)'	System	27 Aug 2020 18:51:59
	System	27 Aug 2020 18:51:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:46', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'acc60ec0-17f0-4ff2-85de-1acee0170e7a' User entered 'No (N)'	System	27 Aug 2020 18:51:59
	System	27 Aug 2020 18:51:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:49', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'acc60ec0-17f0-4ff2-85de-1acee0170e7a'	System	27 Aug 2020 18:51:59
User entered 'None (1)'	System	27 Aug 2020 18:51:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:51:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'acc60ec0-17f0-4ff2-85de-1acee0170e7a' User entered '27 Aug 2020 14:51'	System	27 Aug 2020 18:51:59
	System	27 Aug 2020 18:51:59

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 4'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '9eb815ef-35fb-49e3-810c-f6169092afc3' User entered 'None (1)'	System	28 Aug 2020 19:10:51
	System	28 Aug 2020 19:10:51

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:35', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '9eb815ef-35fb-49e3-810c-f6169092afc3' User entered 'No (N)'	System	28 Aug 2020 19:10:51
	System	28 Aug 2020 19:10:51

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '9eb815ef-35fb-49e3-810c-f6169092afc3' User entered 'No (N)'	System	28 Aug 2020 19:10:51
	System	28 Aug 2020 19:10:51

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '9eb815ef-35fb-49e3-810c-f6169092afc3' User entered 'None (1)'	System	28 Aug 2020 19:10:51
	System	28 Aug 2020 19:10:51

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:10:49', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '9eb815ef-35fb-49e3-810c-f6169092afc3' User entered '28 Aug 2020 15:10'	System	28 Aug 2020 19:10:51
	System	28 Aug 2020 19:10:51

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 5'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '82d4a89b-a1e6-4a72-8ff2-bfd52a4d4810'	System	29 Aug 2020 19:04:34
User entered 'None (1)'	System	29 Aug 2020 19:04:34

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '82d4a89b-a1e6-4a72-8ff2-bfd52a4d4810'	System	29 Aug 2020 19:04:34
User entered 'No (N)'	System	29 Aug 2020 19:04:34

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '82d4a89b-a1e6-4a72-8ff2-bfd52a4d4810' User entered 'No (N)'	System	29 Aug 2020 19:04:34
	System	29 Aug 2020 19:04:34

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '82d4a89b-a1e6-4a72-8ff2-bfd52a4d4810'	System	29 Aug 2020 19:04:34
User entered 'None (1)'	System	29 Aug 2020 19:04:34

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '82d4a89b-a1e6-4a72-8ff2-bfd52a4d4810' User entered '29 Aug 2020 15:04'	System	29 Aug 2020 19:04:34
	System	29 Aug 2020 19:04:34

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 6'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7d2834a-001c-4b84-91b2-1b8b149caad2'	System	30 Aug 2020 20:21:12
User entered 'None (1)'	System	30 Aug 2020 20:21:12

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:20:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7d2834a-001c-4b84-91b2-1b8b149caad2'	System	30 Aug 2020 20:21:12
User entered 'No (N)'	System	30 Aug 2020 20:21:12

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:01', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7d2834a-001c-4b84-91b2-1b8b149caad2'	System	30 Aug 2020 20:21:12
User entered 'No (N)'	System	30 Aug 2020 20:21:12

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7d2834a-001c-4b84-91b2-1b8b149caad2'	System	30 Aug 2020 20:21:12
User entered 'None (1)'	System	30 Aug 2020 20:21:12

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7d2834a-001c-4b84-91b2-1b8b149caad2' User entered '30 Aug 2020 16:21'	System	30 Aug 2020 20:21:12
	System	30 Aug 2020 20:21:12

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 7'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:35', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c521a214-a675-48e1-9f39-b536f344e45e'	System	31 Aug 2020 20:46:54
User entered 'None (1)'	System	31 Aug 2020 20:46:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c521a214-a675-48e1-9f39-b536f344e45e'	System	31 Aug 2020 20:46:54
User entered 'No (N)'	System	31 Aug 2020 20:46:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:41', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c521a214-a675-48e1-9f39-b536f344e45e' User entered 'No (N)'	System	31 Aug 2020 20:46:54
	System	31 Aug 2020 20:46:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c521a214-a675-48e1-9f39-b536f344e45e'	System	31 Aug 2020 20:46:54
User entered 'None (1)'	System	31 Aug 2020 20:46:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:47', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c521a214-a675-48e1-9f39-b536f344e45e' User entered '31 Aug 2020 16:39'	System	31 Aug 2020 20:46:54
	System	31 Aug 2020 20:46:54

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:27', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:34', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:41', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered 'None (0)'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764'	System	25 Aug 2020 14:36:57
User entered 'No (N)'	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T10:36:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2c87fbb1-6dc7-4ed4-ab0d-a65564d28764' User entered '25 Aug 2020 10:36'	System	25 Aug 2020 14:36:57
	System	25 Aug 2020 14:36:57

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 10:29'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 12:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:11:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'None (0)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5' User entered 'No (N)'	System	25 Aug 2020 18:12:26
	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-25T14:12:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a82d0443-5a72-4e5f-af7f-e393e02355e5'	System	25 Aug 2020 18:12:26
User entered '25 Aug 2020 14:12'	System	25 Aug 2020 18:12:26

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Aug 2020 13:54'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 2'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495' User entered 'None (0)'	System	26 Aug 2020 17:03:21
	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495' User entered 'None (0)'	System	26 Aug 2020 17:03:21
	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495'	System	26 Aug 2020 17:03:21
User entered 'No interference with activity (1)'	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:02:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495'	System	26 Aug 2020 17:03:21
User entered 'No interference with activity (1)'	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:03:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495' User entered 'None (0)'	System	26 Aug 2020 17:03:21
	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:03:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495' User entered 'None (0)'	System	26 Aug 2020 17:03:21
	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:03:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495'	System	26 Aug 2020 17:03:21
User entered 'No (N)'	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-26T13:03:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '53feb08e-9ec0-43b0-91fd-522ea8a4b495'	System	26 Aug 2020 17:03:21
User entered '26 Aug 2020 13:03'	System	26 Aug 2020 17:03:21

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 3'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered 'None (0)'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:24', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347'	System	27 Aug 2020 18:52:31
User entered 'No (N)'	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-27T14:52:27', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2f079db9-3d1a-4928-aafb-8635b3c05347' User entered '27 Aug 2020 14:52'	System	27 Aug 2020 18:52:31
	System	27 Aug 2020 18:52:31

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 4'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:29', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'None (0)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered 'No (N)'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-28T15:11:37', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'adf04f38-95b3-41a7-b8eb-7d8c3858afcf' User entered '28 Aug 2020 15:11'	System	28 Aug 2020 19:11:39
	System	28 Aug 2020 19:11:39

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 5'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:37', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:40', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:43', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:47', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:04:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered 'None (0)'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767'	System	29 Aug 2020 19:05:06
User entered 'No (N)'	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-29T15:05:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68b1d7f5-10f3-498d-97f0-4666b2f78767' User entered '29 Aug 2020 15:05'	System	29 Aug 2020 19:05:06
	System	29 Aug 2020 19:05:06

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 6'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'None (0)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered 'No (N)'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-30T16:21:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0d46186-32af-4646-9554-08c918dd6c9c' User entered '30 Aug 2020 16:21'	System	30 Aug 2020 20:21:43
	System	30 Aug 2020 20:21:43

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 7'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:39:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:40:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'None (0)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:40:07', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered 'No (N)'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-08-31T16:40:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '30e6b3ef-fd03-43fb-8de6-2d0c2754bcd9' User entered '31 Aug 2020 16:40'	System	31 Aug 2020 20:47:07
	System	31 Aug 2020 20:47:07

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:12:38

US3202310

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:15:58

US3202310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	10 Nov 2020 19:25:20
User entered '1 Sep 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:15:58

US3202310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:15:58

US3202310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No answer'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:15:58

US3202310

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:16:02

US3202310

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'I'	System	12 Sep 2020 13:16:02

US3202310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:16:19

US3202310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	10 Nov 2020 19:25:26
User entered '8 Sep 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:16:19

US3202310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:16:19

US3202310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:16:19

US3202310

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	12 Sep 2020 13:16:23

US3202310

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:50:23
User entered 'I'	System	12 Sep 2020 13:16:23

US3202310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Sep 2020 17:16:23

US3202310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '15 Sep 2020'	Tiffany Jewell (b) (4)	24 Sep 2020 17:16:23

US3202310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Made (CONTACT MADE)'	Tiffany Jewell (b) (4)	24 Sep 2020 17:16:23

US3202310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	24 Sep 2020 17:16:23

US3202310

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 15:37:52

US3202310

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:22
User entered 'I'	System	23 Sep 2020 15:37:52

US3202310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:01

US3202310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:01

US3202310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[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 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:01

US3202310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'VISIT2'	System	23 Sep 2020 15:38:01

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '10:16'	Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '23 Sep 2020 10:16'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '36.8' C	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '92'	Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'bpm'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '16'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'breaths/min'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '158'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'mmHg'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '88'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'mmHg'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '12:03'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '23 Sep 2020 12:03'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '36.7' C	Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '72'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'bpm'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '16'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'breaths/min'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '164' reason for change: Data Entry Error	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:24:28
User entered '200' reason for change: Data Entry Error	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:24:16
User entered '164'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'mmHg'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '84'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'mmHg'	System	24 Sep 2020 17:23:56

US3202310

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:07

US3202310

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:07

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

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 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '11:20'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '23 Sep 2020 11:20'	System	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'ONCE'	System	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 15:38:27

US3202310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:44

US3202310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:44

US3202310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '10:53'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:44

US3202310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '23 Sep 2020 10:53'	System	23 Sep 2020 15:38:44

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '23 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '10:50'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '23 Sep 2020 10:50'	System	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered empty.	System	23 Sep 2020 15:38:55

US3202310

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	23 Sep 2020 15:38:59

US3202310

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered '1'	System	23 Sep 2020 15:38:59

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8ae7c418-f88e-4ad4-ba7a-fce06d99e41d' User entered 'Yes (Y)'	System	23 Sep 2020 15:42:37
	System	23 Sep 2020 15:42:37

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:24', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8ae7c418-f88e-4ad4-ba7a-fce06d99e41d' User entered '98.3'	System	23 Sep 2020 15:42:37
	System	23 Sep 2020 15:42:37

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8ae7c418-f88e-4ad4-ba7a-fce06d99e41d'	System	23 Sep 2020 15:42:37
User entered 'No (N)'	System	23 Sep 2020 15:42:37

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:35', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8ae7c418-f88e-4ad4-ba7a-fce06d99e41d' User entered '23 Sep 2020 11:42'	System	23 Sep 2020 15:42:37
	System	23 Sep 2020 15:42:37

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 11:40'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 14:10'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:24:34', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '70413395-535e-41b2-bc24-558a0677c781'	System	23 Sep 2020 20:24:49
User entered 'Yes (Y)'	System	23 Sep 2020 20:24:49

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:24:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '70413395-535e-41b2-bc24-558a0677c781' User entered '96.7'	System	23 Sep 2020 20:24:49
	System	23 Sep 2020 20:24:49

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:24:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '70413395-535e-41b2-bc24-558a0677c781'	System	23 Sep 2020 20:24:49
User entered 'No (N)'	System	23 Sep 2020 20:24:49

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:24:46', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '70413395-535e-41b2-bc24-558a0677c781'	System	23 Sep 2020 20:24:49
User entered '23 Sep 2020 16:24'	System	23 Sep 2020 20:24:49

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 15:05'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 2'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8812ba7-657b-454a-97e3-599161112923'	System	24 Sep 2020 17:55:40
User entered 'Yes (Y)'	System	24 Sep 2020 17:55:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8812ba7-657b-454a-97e3-599161112923' User entered '98.5'	System	24 Sep 2020 17:55:40
	System	24 Sep 2020 17:55:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8812ba7-657b-454a-97e3-599161112923'	System	24 Sep 2020 17:55:40
User entered 'No (N)'	System	24 Sep 2020 17:55:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:37', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8812ba7-657b-454a-97e3-599161112923'	System	24 Sep 2020 17:55:40
User entered '24 Sep 2020 13:55'	System	24 Sep 2020 17:55:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 3'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8c91e3ec-0692-4f0c-ab6e-db1772f0f51b' User entered 'Yes (Y)'	System	25 Sep 2020 17:57:40
	System	25 Sep 2020 17:57:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:29', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8c91e3ec-0692-4f0c-ab6e-db1772f0f51b' User entered '97.6'	System	25 Sep 2020 17:57:40
	System	25 Sep 2020 17:57:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8c91e3ec-0692-4f0c-ab6e-db1772f0f51b'	System	25 Sep 2020 17:57:40
User entered 'No (N)'	System	25 Sep 2020 17:57:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:36', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '8c91e3ec-0692-4f0c-ab6e-db1772f0f51b' User entered '25 Sep 2020 13:57'	System	25 Sep 2020 17:57:40
	System	25 Sep 2020 17:57:40

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 4'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:01', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8257c54-fdfa-4306-9aa8-a113ab204af0' User entered 'Yes (Y)'	System	26 Sep 2020 23:12:27
	System	26 Sep 2020 23:12:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8257c54-fdfa-4306-9aa8-a113ab204af0' User entered '97.6'	System	26 Sep 2020 23:12:27
	System	26 Sep 2020 23:12:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8257c54-fdfa-4306-9aa8-a113ab204af0'	System	26 Sep 2020 23:12:27
User entered 'No (N)'	System	26 Sep 2020 23:12:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b8257c54-fdfa-4306-9aa8-a113ab204af0' User entered '26 Sep 2020 19:12'	System	26 Sep 2020 23:12:27
	System	26 Sep 2020 23:12:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 5'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:30:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '07412f65-d772-4c01-92ea-b208e539ca19' User entered 'Yes (Y)'	System	27 Sep 2020 19:31:00
	System	27 Sep 2020 19:31:00

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:30:50', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '07412f65-d772-4c01-92ea-b208e539ca19' User entered '94.5'	System	27 Sep 2020 19:31:00
	System	27 Sep 2020 19:31:00

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:30:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '07412f65-d772-4c01-92ea-b208e539ca19' User entered 'No (N)'	System	27 Sep 2020 19:31:00
	System	27 Sep 2020 19:31:00

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:30:57', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '07412f65-d772-4c01-92ea-b208e539ca19' User entered '27 Sep 2020 15:30'	System	27 Sep 2020 19:31:00
	System	27 Sep 2020 19:31:00

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 6'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aa49eec2-3fec-4522-b282-a23b3f7eac03' User entered 'Yes (Y)'	System	28 Sep 2020 18:03:44
	System	28 Sep 2020 18:03:44

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:36', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aa49eec2-3fec-4522-b282-a23b3f7eac03' User entered '97.7'	System	28 Sep 2020 18:03:44
	System	28 Sep 2020 18:03:44

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aa49eec2-3fec-4522-b282-a23b3f7eac03'	System	28 Sep 2020 18:03:44
User entered 'No (N)'	System	28 Sep 2020 18:03:44

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aa49eec2-3fec-4522-b282-a23b3f7eac03' User entered '28 Sep 2020 14:03'	System	28 Sep 2020 18:03:44
	System	28 Sep 2020 18:03:44

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 7'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '17d0336f-7bc1-44ac-8a40-2258f46881c9' User entered 'Yes (Y)'	System	29 Sep 2020 18:52:45
	System	29 Sep 2020 18:52:45

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:37', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '17d0336f-7bc1-44ac-8a40-2258f46881c9' User entered '97.7'	System	29 Sep 2020 18:52:45
	System	29 Sep 2020 18:52:45

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:39', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '17d0336f-7bc1-44ac-8a40-2258f46881c9' User entered 'No (N)'	System	29 Sep 2020 18:52:45
	System	29 Sep 2020 18:52:45

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '17d0336f-7bc1-44ac-8a40-2258f46881c9' User entered '29 Sep 2020 14:52'	System	29 Sep 2020 18:52:45
	System	29 Sep 2020 18:52:45

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '33d02963-7ffc-4b41-a07b-15aab4e26864'	System	23 Sep 2020 15:43:07
User entered 'None (1)'	System	23 Sep 2020 15:43:07

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:49', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '33d02963-7ffc-4b41-a07b-15aab4e26864' User entered 'No (N)'	System	23 Sep 2020 15:43:07
	System	23 Sep 2020 15:43:07

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '33d02963-7ffc-4b41-a07b-15aab4e26864' User entered 'No (N)'	System	23 Sep 2020 15:43:07
	System	23 Sep 2020 15:43:07

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:42:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '33d02963-7ffc-4b41-a07b-15aab4e26864'	System	23 Sep 2020 15:43:07
User entered 'None (1)'	System	23 Sep 2020 15:43:07

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:04', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '33d02963-7ffc-4b41-a07b-15aab4e26864' User entered '23 Sep 2020 11:43'	System	23 Sep 2020 15:43:07
	System	23 Sep 2020 15:43:07

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 11:40'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 14:10'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:24:58', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3900f5a0-ad2c-42d1-90ad-ff42ecd11c40'	System	23 Sep 2020 20:25:17
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 20:25:17

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3900f5a0-ad2c-42d1-90ad-ff42ecd11c40'	System	23 Sep 2020 20:25:17
User entered 'No (N)'	System	23 Sep 2020 20:25:17

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3900f5a0-ad2c-42d1-90ad-ff42ecd11c40' User entered 'No (N)'	System	23 Sep 2020 20:25:17
	System	23 Sep 2020 20:25:17

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3900f5a0-ad2c-42d1-90ad-ff42ecd11c40'	System	23 Sep 2020 20:25:17
User entered 'None (1)'	System	23 Sep 2020 20:25:17

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3900f5a0-ad2c-42d1-90ad-ff42ecd11c40'	System	23 Sep 2020 20:25:17
User entered '23 Sep 2020 16:25'	System	23 Sep 2020 20:25:17

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 15:05'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 2'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b7f90da3-5702-4a3e-aba7-07461ba92eba' User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:56:09
	System	24 Sep 2020 17:56:09

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b7f90da3-5702-4a3e-aba7-07461ba92eba' User entered 'No (N)'	System	24 Sep 2020 17:56:09
	System	24 Sep 2020 17:56:09

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b7f90da3-5702-4a3e-aba7-07461ba92eba' User entered 'No (N)'	System	24 Sep 2020 17:56:09
	System	24 Sep 2020 17:56:09

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:55:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b7f90da3-5702-4a3e-aba7-07461ba92eba' User entered 'None (1)'	System	24 Sep 2020 17:56:09
	System	24 Sep 2020 17:56:09

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b7f90da3-5702-4a3e-aba7-07461ba92eba' User entered '24 Sep 2020 13:56'	System	24 Sep 2020 17:56:09
	System	24 Sep 2020 17:56:09

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 3'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6f9472bc-29e5-4d17-9396-261f795f294a' User entered 'None (1)'	System	25 Sep 2020 17:58:04
	System	25 Sep 2020 17:58:04

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:48', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6f9472bc-29e5-4d17-9396-261f795f294a' User entered 'No (N)'	System	25 Sep 2020 17:58:04
	System	25 Sep 2020 17:58:04

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:51', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6f9472bc-29e5-4d17-9396-261f795f294a' User entered 'No (N)'	System	25 Sep 2020 17:58:04
	System	25 Sep 2020 17:58:04

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:57:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6f9472bc-29e5-4d17-9396-261f795f294a' User entered 'None (1)'	System	25 Sep 2020 17:58:04
	System	25 Sep 2020 17:58:04

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6f9472bc-29e5-4d17-9396-261f795f294a' User entered '25 Sep 2020 13:58'	System	25 Sep 2020 17:58:04
	System	25 Sep 2020 17:58:04

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 4'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:27', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6c3b9cb9-27ee-4369-b523-aec7f4ac8979'	System	26 Sep 2020 23:12:40
User entered 'None (1)'	System	26 Sep 2020 23:12:40

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6c3b9cb9-27ee-4369-b523-aec7f4ac8979' User entered 'No (N)'	System	26 Sep 2020 23:12:40
	System	26 Sep 2020 23:12:40

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6c3b9cb9-27ee-4369-b523-aec7f4ac8979' User entered 'No (N)'	System	26 Sep 2020 23:12:40
	System	26 Sep 2020 23:12:40

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:36', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6c3b9cb9-27ee-4369-b523-aec7f4ac8979'	System	26 Sep 2020 23:12:40
User entered 'None (1)'	System	26 Sep 2020 23:12:40

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6c3b9cb9-27ee-4369-b523-aec7f4ac8979' User entered '26 Sep 2020 19:12'	System	26 Sep 2020 23:12:40
	System	26 Sep 2020 23:12:40

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 5'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68691ef2-2769-416e-83e0-1ca5232ba098'	System	27 Sep 2020 19:31:19
User entered 'None (1)'	System	27 Sep 2020 19:31:19

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68691ef2-2769-416e-83e0-1ca5232ba098'	System	27 Sep 2020 19:31:19
User entered 'No (N)'	System	27 Sep 2020 19:31:19

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:08', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68691ef2-2769-416e-83e0-1ca5232ba098'	System	27 Sep 2020 19:31:19
User entered 'No (N)'	System	27 Sep 2020 19:31:19

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68691ef2-2769-416e-83e0-1ca5232ba098'	System	27 Sep 2020 19:31:19
User entered 'None (1)'	System	27 Sep 2020 19:31:19

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '68691ef2-2769-416e-83e0-1ca5232ba098' User entered '27 Sep 2020 15:31'	System	27 Sep 2020 19:31:19
	System	27 Sep 2020 19:31:19

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 6'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:46', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '93040173-becb-4151-baed-b3e6d1d90ee7' User entered 'None (1)'	System	28 Sep 2020 18:04:01
	System	28 Sep 2020 18:04:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:50', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '93040173-becb-4151-baed-b3e6d1d90ee7' User entered 'No (N)'	System	28 Sep 2020 18:04:01
	System	28 Sep 2020 18:04:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:52', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '93040173-becb-4151-baed-b3e6d1d90ee7' User entered 'No (N)'	System	28 Sep 2020 18:04:01
	System	28 Sep 2020 18:04:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:54', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '93040173-becb-4151-baed-b3e6d1d90ee7'	System	28 Sep 2020 18:04:01
User entered 'None (1)'	System	28 Sep 2020 18:04:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:03:58', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '93040173-becb-4151-baed-b3e6d1d90ee7' User entered '28 Sep 2020 14:03'	System	28 Sep 2020 18:04:01
	System	28 Sep 2020 18:04:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 7'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:47', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '988b2265-5912-4ec1-99f4-8cb0f77e8a30'	System	29 Sep 2020 18:53:01
User entered 'None (1)'	System	29 Sep 2020 18:53:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:50', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '988b2265-5912-4ec1-99f4-8cb0f77e8a30' User entered 'No (N)'	System	29 Sep 2020 18:53:01
	System	29 Sep 2020 18:53:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '988b2265-5912-4ec1-99f4-8cb0f77e8a30' User entered 'No (N)'	System	29 Sep 2020 18:53:01
	System	29 Sep 2020 18:53:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '988b2265-5912-4ec1-99f4-8cb0f77e8a30'	System	29 Sep 2020 18:53:01
User entered 'None (1)'	System	29 Sep 2020 18:53:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:52:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '988b2265-5912-4ec1-99f4-8cb0f77e8a30' User entered '29 Sep 2020 14:52'	System	29 Sep 2020 18:53:01
	System	29 Sep 2020 18:53:01

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:11', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered 'None (0)'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:30', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7'	System	23 Sep 2020 15:43:36
User entered 'No (N)'	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T11:43:34', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '24943e0d-885c-47bc-ab07-a283f613fdf7' User entered '23 Sep 2020 11:43'	System	23 Sep 2020 15:43:36
	System	23 Sep 2020 15:43:36

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 11:40'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 14:10'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:35', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:38', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'None (0)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:42', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered 'No (N)'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-23T16:25:45', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'df1e4e65-53b2-45e7-9c54-c2de7b8e495e' User entered '23 Sep 2020 16:25'	System	23 Sep 2020 20:25:48
	System	23 Sep 2020 20:25:48

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '23 Sep 2020 15:05'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 2'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:10', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec'	System	24 Sep 2020 17:56:35
User entered 'None (0)'	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec' User entered 'None (0)'	System	24 Sep 2020 17:56:35
	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec' User entered 'None (0)'	System	24 Sep 2020 17:56:35
	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec' User entered 'None (0)'	System	24 Sep 2020 17:56:35
	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec' User entered 'None (0)'	System	24 Sep 2020 17:56:35
	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec' User entered 'None (0)'	System	24 Sep 2020 17:56:35
	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:29', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec'	System	24 Sep 2020 17:56:35
User entered 'No (N)'	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-24T13:56:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f837c623-39ed-40ab-9f2a-c21a1da1d2ec'	System	24 Sep 2020 17:56:35
User entered '24 Sep 2020 13:56'	System	24 Sep 2020 17:56:35

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 3'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:11', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:25', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered 'None (0)'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7'	System	25 Sep 2020 17:58:38
User entered 'No (N)'	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-25T13:58:35', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'e3f026ac-997d-4311-bc2c-9ad9104a82d7' User entered '25 Sep 2020 13:58'	System	25 Sep 2020 17:58:38
	System	25 Sep 2020 17:58:38

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 4'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:43', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:46', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:50', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:56', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:12:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'None (0)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:13:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered 'No (N)'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-26T19:13:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c82e44d6-6a8b-42c4-92af-5ba82afaafe2' User entered '26 Sep 2020 19:13'	System	26 Sep 2020 23:13:08
	System	26 Sep 2020 23:13:08

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 5'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered 'None (0)'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:21', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7'	System	27 Sep 2020 19:31:49
User entered 'None (0)'	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:24', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered 'None (0)'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:27', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered 'None (0)'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered 'None (0)'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:36', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered 'None (0)'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:40', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7'	System	27 Sep 2020 19:31:49
User entered 'No (N)'	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-27T15:31:47', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '76bc94f5-8ade-4e8e-b856-532272c975c7' User entered '27 Sep 2020 15:31'	System	27 Sep 2020 19:31:49
	System	27 Sep 2020 19:31:49

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 6'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:04', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:07', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:12', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'None (0)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered 'No (N)'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-28T14:04:21', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd7388cfc-142c-4898-96f7-88a04a2f155e' User entered '28 Sep 2020 14:04'	System	28 Sep 2020 18:04:22
	System	28 Sep 2020 18:04:22

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	23 Sep 2020 15:38:27
User entered 'Day 7'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:04', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:13', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:16', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered 'None (0)'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734'	System	29 Sep 2020 18:53:34
User entered 'No (N)'	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-09-29T14:53:30', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b6546601-22d3-4bd6-97be-6df5ff628734' User entered '29 Sep 2020 14:53'	System	29 Sep 2020 18:53:34
	System	29 Sep 2020 18:53:34

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:38:27

US3202310

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:38:27

US3202310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	30 Sep 2020 15:49:13

US3202310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '30 Sep 2020'	Lilian Nukuna (b) (4)	30 Sep 2020 15:49:13

US3202310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	30 Sep 2020 15:49:13

US3202310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Lilian Nukuna (b) (4)	30 Sep 2020 15:49:13

US3202310

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	30 Sep 2020 15:49:18

US3202310

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'I'	System	30 Sep 2020 15:49:18

US3202310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	07 Oct 2020 18:06:52

US3202310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	10 Nov 2020 19:25:57
User entered '7 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	07 Oct 2020 18:06:52

US3202310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	07 Oct 2020 18:06:52

US3202310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Lilian Nukuna (b) (4)	07 Oct 2020 18:06:52

US3202310

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	07 Oct 2020 18:06:56

US3202310

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'I'	System	07 Oct 2020 18:06:56

US3202310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	14 Oct 2020 13:47:34

US3202310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered '14 Oct 2020'	Lilian Nukuna (b) (4)	14 Oct 2020 13:47:34

US3202310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	14 Oct 2020 13:47:34

US3202310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered empty.	Lilian Nukuna (b) (4)	14 Oct 2020 13:47:34

US3202310

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	14 Oct 2020 13:47:41

US3202310

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'I'	System	14 Oct 2020 13:47:41

US3202310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 17:16:13

US3202310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 17:16:13
	(b) (4)	

US3202310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[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 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 17:16:13

US3202310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'VISIT3'	System	13 Mar 2021 17:16:13

US3202310

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:21:03
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Nov 2020 16:44:12

US3202310

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'I'	System	18 Nov 2020 16:44:12

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 64'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:08:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64'	System	27 Oct 2020 16:09:27
User entered 'Yes (Y)'	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:08:40', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64'	System	27 Oct 2020 16:09:27
User entered 'No (N)'	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:08:46', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64'	System	27 Oct 2020 16:09:27
User entered 'No (N)'	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:08:55', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64'	System	27 Oct 2020 16:09:27
User entered 'Yes (Y)'	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:09:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64'	System	27 Oct 2020 16:09:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-10-27T12:09:14', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '85a8756a-e04a-4835-94a0-ef2a96be4b64' User entered '27 Oct 2020 12:09:14'	System	27 Oct 2020 16:09:27
	System	27 Oct 2020 16:09:27

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 71'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-01T14:33:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ed68d572-89d1-4a0d-b6d9-8b1695664dea'	System	01 Nov 2020 19:33:45
User entered 'No (N)'	System	01 Nov 2020 19:33:45

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-01T14:33:29', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ed68d572-89d1-4a0d-b6d9-8b1695664dea'	System	01 Nov 2020 19:33:45
User entered 'No (N)'	System	01 Nov 2020 19:33:45

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-01T14:33:37', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ed68d572-89d1-4a0d-b6d9-8b1695664dea' User entered '01 Nov 2020 14:33:37'	System	01 Nov 2020 19:33:45
	System	01 Nov 2020 19:33:45

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered 'Day 78'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-08T10:19:17', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1bc1a07c-94ed-4b47-b293-5152d675d20c' User entered 'No (N)'	System	08 Nov 2020 15:19:32
	System	08 Nov 2020 15:19:32

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-08T10:19:24', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1bc1a07c-94ed-4b47-b293-5152d675d20c' User entered 'No (N)'	System	08 Nov 2020 15:19:32
	System	08 Nov 2020 15:19:32

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-08T10:19:30', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1bc1a07c-94ed-4b47-b293-5152d675d20c' User entered '08 Nov 2020 10:19:30'	System	08 Nov 2020 15:19:32
	System	08 Nov 2020 15:19:32

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 14:12:38

US3202310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:45:54
Data entry locked.	System	25 Aug 2020 14:12:38
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 14:12:38

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-22T07:53:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6087d2c1-b634-4c2b-ac22-d7032884ab66'	System	22 Nov 2020 12:54:02
User entered 'No (N)'	System	22 Nov 2020 12:54:02

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-22T07:53:52', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6087d2c1-b634-4c2b-ac22-d7032884ab66'	System	22 Nov 2020 12:54:02
User entered 'No (N)'	System	22 Nov 2020 12:54:02

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-22T07:53:58', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6087d2c1-b634-4c2b-ac22-d7032884ab66'	System	22 Nov 2020 12:54:02
User entered '22 Nov 2020 07:53:58'	System	22 Nov 2020 12:54:02

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-27T09:00:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aab22493-4d5a-4319-9ad2-d5f9e993994d' User entered 'No (N)'	System	27 Nov 2020 14:00:12
	System	27 Nov 2020 14:00:12

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-27T09:00:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aab22493-4d5a-4319-9ad2-d5f9e993994d' User entered 'No (N)'	System	27 Nov 2020 14:00:12

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-11-27T09:00:10', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'aab22493-4d5a-4319-9ad2-d5f9e993994d' User entered '27 Nov 2020 09:00:10'	System	27 Nov 2020 14:00:12
	System	27 Nov 2020 14:00:12

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-03T13:11:33', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b9fb8e3e-d6dd-4e26-afdc-dbf931ad6cf3' User entered 'No (N)'	System	03 Dec 2020 18:11:46
	System	03 Dec 2020 18:11:46

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-03T13:11:40', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b9fb8e3e-d6dd-4e26-afdc-dbf931ad6cf3' User entered 'No (N)'	System	03 Dec 2020 18:11:46

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-03T13:11:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b9fb8e3e-d6dd-4e26-afdc-dbf931ad6cf3' User entered '03 Dec 2020 13:11:44'	System	03 Dec 2020 18:11:46
	System	03 Dec 2020 18:11:46

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-10T11:13:44', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd0a6417a-470c-46a9-b913-c44c07cde51a' User entered 'No (N)'	System	10 Dec 2020 16:13:57
	System	10 Dec 2020 16:13:57

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-10T11:13:48', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd0a6417a-470c-46a9-b913-c44c07cde51a' User entered 'No (N)'	System	10 Dec 2020 16:13:57
	System	10 Dec 2020 16:13:57

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-10T11:13:53', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'd0a6417a-470c-46a9-b913-c44c07cde51a' User entered '10 Dec 2020 11:13:53'	System	10 Dec 2020 16:13:57
	System	10 Dec 2020 16:13:57

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-17T17:38:49', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a129c581-789e-4882-895f-90237822fe42'	System	17 Dec 2020 22:39:09
User entered 'No (N)'	System	17 Dec 2020 22:39:09

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-17T17:38:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a129c581-789e-4882-895f-90237822fe42'	System	17 Dec 2020 22:39:09
User entered 'No (N)'	System	17 Dec 2020 22:39:09

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-17T17:39:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a129c581-789e-4882-895f-90237822fe42' User entered '17 Dec 2020 17:39:03'	System	17 Dec 2020 22:39:09
	System	17 Dec 2020 22:39:09

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-24T02:23:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a10c5958-478b-4cc5-8f21-3e2b4ff93a62'	System	24 Dec 2020 07:23:36
User entered 'No (N)'	System	24 Dec 2020 07:23:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-24T02:23:24', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a10c5958-478b-4cc5-8f21-3e2b4ff93a62'	System	24 Dec 2020 07:23:36
User entered 'No (N)'	System	24 Dec 2020 07:23:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-24T02:23:32', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a10c5958-478b-4cc5-8f21-3e2b4ff93a62' User entered '24 Dec 2020 02:23:32'	System	24 Dec 2020 07:23:36
	System	24 Dec 2020 07:23:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-31T00:17:02', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0cc5ee6-9f22-4ab8-8afd-4aaa254d11a4' User entered 'No (N)'	System	31 Dec 2020 05:17:25
	System	31 Dec 2020 05:17:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-31T00:17:16', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0cc5ee6-9f22-4ab8-8afd-4aaa254d11a4'	System	31 Dec 2020 05:17:25
User entered 'No (N)'	System	31 Dec 2020 05:17:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2020-12-31T00:17:22', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'a0cc5ee6-9f22-4ab8-8afd-4aaa254d11a4' User entered '31 Dec 2020 00:17:22'	System	31 Dec 2020 05:17:25
	System	31 Dec 2020 05:17:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-07T00:05:54', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '353d7966-38b9-4749-b98f-443943d255f4'	System	07 Jan 2021 05:06:25
User entered 'No (N)'	System	07 Jan 2021 05:06:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-07T00:06:11', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '353d7966-38b9-4749-b98f-443943d255f4'	System	07 Jan 2021 05:06:25
User entered 'No (N)'	System	07 Jan 2021 05:06:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-07T00:06:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '353d7966-38b9-4749-b98f-443943d255f4' User entered '07 Jan 2021 00:06:20'	System	07 Jan 2021 05:06:25
	System	07 Jan 2021 05:06:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-14T07:56:13', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '924e26fc-0b9d-4645-898d-1b29721abd29' User entered 'No (N)'	System	14 Jan 2021 12:56:25
	System	14 Jan 2021 12:56:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-14T07:56:19', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '924e26fc-0b9d-4645-898d-1b29721abd29'	System	14 Jan 2021 12:56:25
User entered 'No (N)'	System	14 Jan 2021 12:56:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-14T07:56:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '924e26fc-0b9d-4645-898d-1b29721abd29' User entered '14 Jan 2021 07:56:23'	System	14 Jan 2021 12:56:25
	System	14 Jan 2021 12:56:25

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-21T00:40:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7337969a-dc89-43ca-a6cb-b518f3688a0d' User entered 'No (N)'	System	21 Jan 2021 05:40:36
	System	21 Jan 2021 05:40:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-21T00:40:26', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7337969a-dc89-43ca-a6cb-b518f3688a0d' User entered 'No (N)'	System	21 Jan 2021 05:40:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-21T00:40:31', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '7337969a-dc89-43ca-a6cb-b518f3688a0d' User entered '21 Jan 2021 00:40:31'	System	21 Jan 2021 05:40:36
	System	21 Jan 2021 05:40:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-28T07:20:59', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '48b804b3-72da-4aa4-8d95-83d1a2367839' User entered 'No (N)'	System	01 Feb 2021 14:30:40
	System	01 Feb 2021 14:30:40

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-28T07:21:05', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '48b804b3-72da-4aa4-8d95-83d1a2367839'	System	01 Feb 2021 14:30:40
User entered 'No (N)'	System	01 Feb 2021 14:30:40

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-01-28T07:21:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '48b804b3-72da-4aa4-8d95-83d1a2367839'	System	01 Feb 2021 14:30:40
User entered '28 Jan 2021 07:21:09'	System	01 Feb 2021 14:30:40

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-04T13:25:18', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c62b42b4-653d-4e0b-a681-4f4a12a01ada' User entered 'No (N)'	System	04 Feb 2021 18:26:18
	System	04 Feb 2021 18:26:18

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-04T13:25:23', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c62b42b4-653d-4e0b-a681-4f4a12a01ada' User entered 'No (N)'	System	04 Feb 2021 18:26:18
	System	04 Feb 2021 18:26:18

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-04T13:25:28', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c62b42b4-653d-4e0b-a681-4f4a12a01ada' User entered '04 Feb 2021 13:25:28'	System	04 Feb 2021 18:26:18
	System	04 Feb 2021 18:26:18

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-11T07:56:09', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6352e2d8-4ad2-4d93-b1df-f99123a46eb1' User entered 'No (N)'	System	11 Feb 2021 12:56:26
	System	11 Feb 2021 12:56:26

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-11T07:56:15', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6352e2d8-4ad2-4d93-b1df-f99123a46eb1' User entered 'No (N)'	System	11 Feb 2021 12:56:26

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-11T07:56:20', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '6352e2d8-4ad2-4d93-b1df-f99123a46eb1' User entered '11 Feb 2021 07:56:20'	System	11 Feb 2021 12:56:26
	System	11 Feb 2021 12:56:26

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-18T14:47:58', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '489b13a8-999d-453f-a871-5e075f01c6dc' User entered 'No (N)'	System	18 Feb 2021 19:48:15
	System	18 Feb 2021 19:48:15

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-18T14:48:03', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '489b13a8-999d-453f-a871-5e075f01c6dc' User entered 'No (N)'	System	18 Feb 2021 19:48:15

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-18T14:48:06', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '489b13a8-999d-453f-a871-5e075f01c6dc' User entered '18 Feb 2021 14:48:06'	System	18 Feb 2021 19:48:15
	System	18 Feb 2021 19:48:15

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-27T12:36:14-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b03bcf4e-c445-451f-b0a9-3fb113b5f643'	System	04 Mar 2021 12:50:36
User entered 'No (N)'	System	04 Mar 2021 12:50:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-27T12:36:19-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b03bcf4e-c445-451f-b0a9-3fb113b5f643'	System	04 Mar 2021 12:50:36
User entered 'No (N)'	System	04 Mar 2021 12:50:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-02-27T12:36:23-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'b03bcf4e-c445-451f-b0a9-3fb113b5f643'	System	04 Mar 2021 12:50:36
User entered '27 Feb 2021 17:36:23'	System	04 Mar 2021 12:50:36

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-04T07:50:48-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '0073711e-3dd1-4bc6-979f-c70b6d0c8fa2'	System	04 Mar 2021 12:51:42
User entered 'No (N)'	System	04 Mar 2021 12:51:42

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-04T07:51:32-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '0073711e-3dd1-4bc6-979f-c70b6d0c8fa2'	System	04 Mar 2021 12:51:42
User entered 'No (N)'	System	04 Mar 2021 12:51:42

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-04T07:51:38-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '0073711e-3dd1-4bc6-979f-c70b6d0c8fa2' User entered '04 Mar 2021 07:51:38'	System	04 Mar 2021 12:51:42
	System	04 Mar 2021 12:51:42

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-11T07:59:32-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1de7e244-d10d-4e71-93d8-a2aca250a778'	System	18 Mar 2021 04:05:17
User entered 'No (N)'	System	18 Mar 2021 04:05:17

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-11T07:59:40-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1de7e244-d10d-4e71-93d8-a2aca250a778'	System	18 Mar 2021 04:05:17
User entered 'No (N)'	System	18 Mar 2021 04:05:17

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-11T07:59:49-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1de7e244-d10d-4e71-93d8-a2aca250a778'	System	18 Mar 2021 04:05:17
User entered '11 Mar 2021 07:59:49'	System	18 Mar 2021 04:05:17

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-18T00:03:47-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3a0746df-9fb4-4384-ac1b-68ed1da5aac5'	System	25 Mar 2021 06:25:37
User entered 'No (N)'	System	25 Mar 2021 06:25:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-18T00:03:57-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3a0746df-9fb4-4384-ac1b-68ed1da5aac5'	System	25 Mar 2021 06:25:37
User entered 'No (N)'	System	25 Mar 2021 06:25:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-18T00:04:02-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '3a0746df-9fb4-4384-ac1b-68ed1da5aac5' User entered '18 Mar 2021 00:04:02'	System	25 Mar 2021 06:25:37
	System	25 Mar 2021 06:25:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-25T02:25:39-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2a3288a2-ae7a-4aeb-864b-e1d3ad68a25c'	System	25 Mar 2021 06:25:54
User entered 'No (N)'	System	25 Mar 2021 06:25:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-25T02:25:46-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2a3288a2-ae7a-4aeb-864b-e1d3ad68a25c'	System	25 Mar 2021 06:25:54
User entered 'No (N)'	System	25 Mar 2021 06:25:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-25T02:25:51-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '2a3288a2-ae7a-4aeb-864b-e1d3ad68a25c' User entered '25 Mar 2021 02:25:51'	System	25 Mar 2021 06:25:54
	System	25 Mar 2021 06:25:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-01T21:29:02-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c6256221-981f-4bf4-908c-0a708c69d78c'	System	02 Apr 2021 01:29:29
User entered 'No (N)'	System	02 Apr 2021 01:29:29

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-01T21:29:09-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c6256221-981f-4bf4-908c-0a708c69d78c'	System	02 Apr 2021 01:29:29
User entered 'No (N)'	System	02 Apr 2021 01:29:29

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-01T21:29:13-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'c6256221-981f-4bf4-908c-0a708c69d78c'	System	02 Apr 2021 01:29:29
User entered '01 Apr 2021 21:29:13'	System	02 Apr 2021 01:29:29

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-08T08:09:23-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '964df96e-972d-4be0-a207-19f228c5f0e2'	System	08 Apr 2021 12:09:37
User entered 'No (N)'	System	08 Apr 2021 12:09:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-08T08:09:30-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '964df96e-972d-4be0-a207-19f228c5f0e2'	System	08 Apr 2021 12:09:37
User entered 'No (N)'	System	08 Apr 2021 12:09:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-08T08:09:33-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '964df96e-972d-4be0-a207-19f228c5f0e2'	System	08 Apr 2021 12:09:37
User entered '08 Apr 2021 08:09:33'	System	08 Apr 2021 12:09:37

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-17T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ee5cdaf8-1a65-4092-bee0-cb4b9b4b2109' User entered 'No (N)'	System	22 Apr 2021 12:11:54
	System	22 Apr 2021 12:11:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-17T12:00:24-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ee5cdaf8-1a65-4092-bee0-cb4b9b4b2109'	System	22 Apr 2021 12:11:54
User entered 'No (N)'	System	22 Apr 2021 12:11:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-17T12:00:28-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'ee5cdaf8-1a65-4092-bee0-cb4b9b4b2109'	System	22 Apr 2021 12:11:54
User entered '17 Apr 2021 12:00:28'	System	22 Apr 2021 12:11:54

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-22T08:11:54-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f5ca14a5-5b40-4add-9976-9a2e580d7cb0'	System	22 Apr 2021 12:12:08
User entered 'No (N)'	System	22 Apr 2021 12:12:08

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-22T08:11:57-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f5ca14a5-5b40-4add-9976-9a2e580d7cb0'	System	22 Apr 2021 12:12:08
User entered 'No (N)'	System	22 Apr 2021 12:12:08

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-22T08:12:01-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: 'f5ca14a5-5b40-4add-9976-9a2e580d7cb0'	System	22 Apr 2021 12:12:08
User entered '22 Apr 2021 08:12:01'	System	22 Apr 2021 12:12:08

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:36:12-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04'	System	29 Apr 2021 19:38:56
User entered 'Yes (Y)'	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

Have you been exposed to someone with 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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:36:17-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04'	System	29 Apr 2021 19:38:56
User entered 'No (N)'	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:36:23-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04' User entered 'No (N)'	System	29 Apr 2021 19:38:56
	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[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 (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:36:32-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04'	System	29 Apr 2021 19:38:56
User entered 'Yes (Y)'	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:36:55-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04'	System	29 Apr 2021 19:38:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-04-29T15:38:43-04:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '1c44da58-0b69-41d0-a244-b42019f67a04'	System	29 Apr 2021 19:38:56
User entered '29 Apr 2021 15:38:43'	System	29 Apr 2021 19:38:56

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:12:48

US3202310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:12:48
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:12:48

US3202310

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-04T07:51:48-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '177dc29f-3a0e-4c95-bec6-cdce4e4f36e6'	System	11 Mar 2021 12:59:25
User entered 'No (N)'	System	11 Mar 2021 12:59:25

US3202310

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:07:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E08EA8A7-AA04-47B4-8CE4-C99411EFD916)', Time: '2021-03-04T07:51:57-05:00', User OID: 'PatientReportedOutcome (US3202310)', ODM File OID: '177dc29f-3a0e-4c95-bec6-cdce4e4f36e6'	System	11 Mar 2021 12:59:25
User entered '04 Mar 2021 07:51:57'	System	11 Mar 2021 12:59:25

US3202310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Nov 2020 16:44:24

US3202310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered '18 Nov 2020'	(b) (4) Lilian Nukuna (b) (4)	18 Nov 2020 16:44:24

US3202310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	18 Nov 2020 16:44:24

US3202310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered empty.	Lilian Nukuna (b) (4)	18 Nov 2020 16:44:24

US3202310

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:51:17
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Nov 2020 16:44:30

US3202310

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:35:17
User entered 'I'	System	18 Nov 2020 16:44:30

US3202310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Dec 2020 18:37:46

US3202310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	20 Dec 2020 18:37:46

US3202310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Dec 2020 18:37:46

US3202310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 18:37:46

US3202310

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Dec 2020 18:37:49

US3202310

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User entered 'I'	System	20 Dec 2020 18:37:49

US3202310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	21 Jan 2021 20:21:03

US3202310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '21 Jan 2021'	Lilian Nukuna (b) (4)	21 Jan 2021 20:21:03

US3202310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	21 Jan 2021 20:21:03

US3202310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered empty.	Lilian Nukuna (b) (4)	21 Jan 2021 20:21:03

US3202310

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	21 Jan 2021 20:21:10

US3202310

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User entered 'I'	System	21 Jan 2021 20:21:10

US3202310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	23 Feb 2021 22:00:26

US3202310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '23 Feb 2021'	(b) (4) zackery harmon (b) (4)	23 Feb 2021 22:00:26

US3202310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	23 Feb 2021 22:00:26

US3202310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered empty.	(b) (4) zackery harmon (b) (4)	23 Feb 2021 22:00:26
	(b) (4)	

US3202310

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	23 Feb 2021 22:00:31

US3202310

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:40:39
User entered 'I'	System	23 Feb 2021 22:00:31

US3202310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:15:59

US3202310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered '31 Mar 2021'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:15:59

US3202310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:15:59

US3202310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered 'VISIT4'	System	06 Apr 2021 14:15:59

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered empty.	System	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered empty.	System	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered empty.	System	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered empty.	System	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:06
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered empty.	System	06 Apr 2021 14:16:05

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50

US3202310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50

US3202310

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:10

US3202310

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered empty.	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:10

US3202310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 14:16:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	06 Apr 2021 14:16:46
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 14:16:30
User entered empty.	Teresa Deese (b) (4)	06 Apr 2021 14:16:30

US3202310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '31 Mar 2021'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:30

US3202310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '10:10'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:30

US3202310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered '31 Mar 2021 10:10'	System	06 Apr 2021 14:16:30

US3202310

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 14:16:14

US3202310

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:50
User entered 'I'	System	06 Apr 2021 14:16:14

US3202310

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:41:48

US3202310

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '5 Feb 2021'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:41:48

US3202310

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:41:48

US3202310

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 19:41:48

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:27:44

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:27:44

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '5 Feb 2021'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User entered empty.	System	05 Feb 2021 19:42:10

US3202310

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User entered empty.	System	05 Feb 2021 19:42:10

US3202310

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:23

US3202310

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 19:42:28
User entered '5 Feb 2021' reason for change: Data Entry Error	System	05 Feb 2021 19:42:28
User opened query 'Data is required. Please provide.' (Site from System).	Teresa Deese (b) (4)	05 Feb 2021 19:42:23
User entered empty.	System	05 Feb 2021 19:42:23

US3202310

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '13:30'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:23

US3202310

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User entered '5 Feb 2021 13:30'	System	05 Feb 2021 19:42:28
User entered empty.	System	05 Feb 2021 19:42:23

US3202310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:38

US3202310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '5 Feb 2021'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:38

US3202310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '13:27'	(b) (4) Teresa Deese (b) (4)	05 Feb 2021 19:42:38

US3202310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:12
User entered '5 Feb 2021 13:27'	System	05 Feb 2021 19:42:38

US3202310

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:46:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:14
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:07:22
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:16:33

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:18
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:53:51
User entered	System	29 Oct 2020 14:53:47
'USA-US128-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 14:53:47

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:55:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:31:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:31:31
Data point term sent to Coder	System	12 Nov 2020 14:47:01
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Nov 2020 14:46:08
Coding entries removed.	Erica Osmundsen (b) (4)	12 Nov 2020 14:46:08
User entered 'WORSENING OF HIATAL HERNIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:14:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:14:44
Data point term sent to Coder	System	28 Oct 2020 16:41:10
User entered 'hiatal hernia flare up'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:27
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:29
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
User closed query 'PV Query: Please consider updating the onset date to the day the subject began experiencing symptoms from the hiatal hernia flare-up.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:20:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:55:07
User closed query 'source = 08Oct2020, Please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:04:10
Query 'source = 08Oct2020, Please verify' answered with 'PER SAFETY PHONE CALL 43 AND CON MEDS FORM DATE OF ONSET IS CORRECTED AND VERIFIED TO 06 OCT 2020' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:01:54
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:01:43
Query 'PV Query: Please consider updating the onset date to the day the subject began experiencing symptoms from the hiatal hernia flare-up.' answered with 'DATED UPDATED TO ONSET OF FLARE UP' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:41:21
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 20:40:17
User opened query 'source = 08Oct2020, Please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:20:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:20:11
User opened query 'PV Query: Please consider updating the onset date to the day the subject began experiencing symptoms from the hiatal hernia flare-up.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:50:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:32
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:34
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:39:45
User closed query 'As hernia repair was completed on 23Oct2021, please verify end date' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:39:43
Query 'As hernia repair was completed on 23Oct2021, please verify end date' answered with 'SUBJECT WAS CONTINUING TO RECOVER THROUGH 24OCT2021 AND MEDICATIONS FOR THIS INDICATION CONTINUED THROUGH THE 24OCT2021 SO WE PUT THE END DATE OF THE AE AS THE DATE OF DISCHARGE AND FULL EVENT RESOLUTION AND DATE THAT TREATMENT FOR THE AE WAS NO LONGER NEEDED.' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 17:32:23
User opened query 'As hernia repair was completed on 23Oct2021, please verify end date' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:18:42
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
User closed query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Hiatal Hernia was performed on 23Oct2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:08:13
Query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Hiatal Hernia was performed on 23Oct2020. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'done; see comments below' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:29:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:30:43
User opened query 'Per DM CLR: Please review the End date of this AE as it was noted that a procedure of Hiatal Hernia was performed on 23Oct2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 19:23:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:38
User entered '24 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:43
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:36:56
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:36:59
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:01
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:04
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:06
User entered '24 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:13
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:16
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:20
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:22
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:23:52
Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Erica Osmundsen (b) (4)	23 Nov 2020 21:22:29
DataPoint Un-verified.	Erica Osmundsen (b) (4)	23 Nov 2020 21:22:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Nov 2020 21:22:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:17:59
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 18:17:58
User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:57:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:24
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:27
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:29
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:30
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) 	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:37:36
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:16:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:19:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'CT DIAGNOSIS OF TYPE 2 HERNIA' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:39:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:50:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:37
User entered 'Subject notified us that she had a flare up of hiatal hernia and had hiatal hernia repair surgery on 23 Oct 2020 which required overnight hospitalization. Subject was discharged 24 Oct 2020.'	(b) (4), (b) (6)	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 16:40:39

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Herpes zoster - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 23:25:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 23:25:51
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 20:07:10
User entered 'herpes zoster'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '28 Apr 2021'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 20:06:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 20:06:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Apr 2021 20:06:54
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 20:06:47
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'I'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 20:06:47

US3202310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:46:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:06:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:46:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:56:21
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:05:00

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 13:07:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 13:07:49
Data point term sent to Coder	System	12 Sep 2020 13:06:19
User entered 'Atorvastatin'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:05:59

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Hypercholesterolemia'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered '80'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'I'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:05:59
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 13:05:59

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 13:05:59

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 13:05:59

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:53:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:53:40
Data point term sent to Coder	System	12 Sep 2020 13:07:20
User entered 'Prilosec'	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 13:06:29

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Gastritis'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered '40'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'UN Mar 2020'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:06:29
	(b) (4)	

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 13:06:29

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 13:06:29

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 13:06:29

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:05:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:05:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:57:19
Data point term sent to Coder	System	12 Nov 2020 14:53:08
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).	System	12 Nov 2020 14:52:27
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' answered with 'DONE' (Site from System).	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:27
User entered 'MOTRIN (IBUPROFEN)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:21
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).	Coder Import (b) (4)	06 Nov 2020 11:03:44
Data point term sent to Coder	System	28 Oct 2020 16:42:12
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 16:41:46

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:14:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:14:15
Data point term sent to Coder	System	07 Oct 2020 18:12:38
User entered 'motrin'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:21
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:22
User entered 'WORSENING OF HIATAL HERNIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:21
User entered 'HIATAL HERNIA' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:41:46
User entered 'acute hiatal hernia'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:25
User entered '400'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:27
User entered 'mg (mg)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:57:30
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:44
Query 'per source x1, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:10:35
User opened query 'per source x1, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:57:51
User entered 'as needed (PRN)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:21
User entered 'once (ONCE)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:46
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:48
User entered 'Oral (ORAL)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:50
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:52
User entered '6 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:55
User entered '0'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:57
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:21
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:10:59
User entered '24 Oct 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:52:21
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:01
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User entered empty.	System	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User entered empty.	System	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:26
User entered empty.	System	07 Oct 2020 18:12:35

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 19:08:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	12 Nov 2020 19:08:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:58:49
Data point term sent to Coder	System	12 Nov 2020 14:52:07
Coding entries removed.	Erica Osmundsen (b) (4)	12 Nov 2020 14:51:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 20:28:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	07 Oct 2020 20:28:51
Data point term sent to Coder	System	07 Oct 2020 18:14:42
User entered 'Zofran'	Lilian Nukuna (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:58:52
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:58:55
User entered 'WORSENING OF HIATAL HERNIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:51:19
User entered 'hiatal hernia'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:05
User entered '4'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:08
User entered 'mg (mg)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:12
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:15
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	12 Nov 2020 14:51:26
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	12 Nov 2020 14:51:26
User entered 'as needed (PRN)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:51:26
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	12 Nov 2020 14:51:19
User entered 'once (ONCE)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:17
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:19
User entered 'Oral (ORAL)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:21
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:23
User entered '6 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:26
User entered '0'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:28
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:51:19
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:30
User entered '24 Oct 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:51:19
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:11:32
User entered 'No (N)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User entered empty.	System	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User entered empty.	System	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:32
User entered empty.	System	07 Oct 2020 18:13:42

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 15:35:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 15:35:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:00:10
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:00:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:00:04
User closed query 'source = general anesthesia, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:59:53
Data point term sent to Coder	System	12 Nov 2020 14:51:04
Query 'source = general anesthesia, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:09
Data point term sent to Coder	System	12 Nov 2020 14:50:04
Coding entries removed.	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:02
User entered 'GENERAL ANESTHESIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:02
User opened query 'source = general anesthesia, please verify' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:16
Query 'please update details when additional hospital records come in.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:00
User opened query 'please update details when additional hospital records come in.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:34

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 16:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 16:38:49
Data point term sent to Coder	System	28 Oct 2020 16:51:34
Data point term sent to Coder	System	28 Oct 2020 16:44:19
User entered 'unknown anesthesia'	(b) (4), (b) (6) (b) (4) (b) (4)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:16
User entered 'WORSENING OF HIATAL HERNIA' reason for change: New Information	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:32
User entered 'hiatal hernia flare up' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:50:56
User entered 'anesthesia for hiatal hernia repair'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:18
User entered 'UNK'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:20
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:22
User entered 'unknown'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:33
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:35
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:39
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:43
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:45
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User entered empty.	System	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User entered empty.	System	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:37
User entered empty.	System	28 Oct 2020 16:44:07

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEF AZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:04:46
Data point term sent to Coder	System	01 Feb 2021 21:32:52
Coding entries removed.	Teresa Deese (b) (4)	01 Feb 2021 21:32:05
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEF AZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 01:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 01:49:15
Data point term sent to Coder	System	23 Nov 2020 21:29:29
User closed query 'CDM-Coding: The trade name ANCEF can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. '(Site from System).	System	23 Nov 2020 21:29:02
Query 'CDM-Coding: The trade name ANCEF can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name.	Erica Osmundsen (b) (4)	23 Nov 2020 21:29:02

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

Name of Medication

Audit	User	Time (GMT)
' answered with 'ADDED' (Site from System). DataPoint Un-verified.	Erica Osmundsen (b) (4)	23 Nov 2020 21:28:43
User entered 'ANCEF (cefazolin)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Nov 2020 21:28:43
User opened query 'CDM-Coding: The trade name ANCEF can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	13 Nov 2020 00:15:37
Data point term sent to Coder	System	12 Nov 2020 14:51:05
Coding entries removed.	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:24:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEFRADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:34:58
User coded data point as Term Coded data point by User: (b) (6) - version	Coder Import (b) (4)	30 Oct 2020 17:34:58
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Oct 2020 16:50:33
User entered 'Ancef'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:19:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User closed query 'per source records - antibiotic prophylaxis, please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 00:11:06
Query 'per source records - antibiotic prophylaxis, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	01 Feb 2021 21:31:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 21:31:41
User opened query 'per source records - antibiotic prophylaxis, please verify' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:31:51
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:31:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:24:43
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:19:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:07:20
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:32:12
User entered 'surgery infection prophylaxis' reason for change: New Information	Teresa Deese (b) (4)	01 Feb 2021 21:32:05
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:31:22
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:29:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:01:01
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:48
User entered 'WORSENING OF HIATAL HERNIA' reason for change: New Information	Erica Osmundsen (b) (4)	12 Nov 2020 14:50:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:24:41
User entered 'hiatal hernia flare up'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:45
User entered '2'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:48
User entered 'g (g)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:50
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:52
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:55
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:24:59
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:25:01
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:25:04
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:25:06
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:25:08
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:25:10
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User entered empty.	System	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User entered empty.	System	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:46
User entered empty.	System	28 Oct 2020 16:49:37

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:26:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:26:09
Data point term sent to Coder	System	29 Apr 2021 20:08:11
User entered 'valacyclovir'	Teresa Deese (b) (4) (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'herpes zoster'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '1'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'g (g)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '28 Apr 2021'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	01 May 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 20:07:47

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:46:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Mar 2021 12:56:01
User closed query 'This is the monitor. Per eDC guidelines only treatment procedures should be captured, Not diagnostic. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 12:55:40
Query 'This is the monitor. Per eDC guidelines only treatment procedures should be captured, Not diagnostic. Please verify and update.' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	19 Mar 2021 17:01:29
DataPoint Un-verified.	Teresa Deese (b) (4)	19 Mar 2021 17:01:16
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Mar 2021 17:01:16
User opened query 'This is the monitor. Per eDC guidelines only treatment procedures should be captured, Not diagnostic. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:48:30
User closed query 'as abdominal CT was diagnostic it should not be captured in eDC. Please verify ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:48:30
Query 'as abdominal CT was diagnostic it should not be captured in eDC. Please verify ' answered with 'we were told by the monitor to remove. please have her notify us if you decide differently' (Site from CRA).	Teresa Deese (b) (4)	01 Feb 2021 21:32:50
User opened query 'as abdominal CT was diagnostic it should not be captured in eDC. Please verify ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:38:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:31:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:51:05
User entered 'No (N)'	Tiffany Jewell (b) (4)	12 Sep 2020 13:16:41
	(b) (4)	

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:26
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:51:46

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:26
User entered 'DAVINCI HIATAL HERNIA REPAIR' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 14:47:08
User entered 'hiatal hernia flare up repair'	(b) (4), (b) (6)	28 Oct 2020 16:51:46

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:26
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	28 Oct 2020 16:51:46

US3202310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:26
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:51:46

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'USA-US128-2020-MRNA-1273-P301000005'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Mark'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'McKenzie'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '6035 SHALLOWFORD ROAD SUITE 109' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '6035 Shallowford Road suite 109'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'CHATTANOOGA' reason for change:	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
Data Entry Error		
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'TN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'TN'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '37421' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '37421'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'US'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 19:48:20
User entered '2'	System	12 Nov 2020 17:20:58
User entered '1'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'USA-US128-2020-MRNA-1273-P301000005'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Mark'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'McKenzie'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '6035 SHALLOWFORD ROAD SUITE 109' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '6035 Shallowford Road suite 109'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'CHATTANOOGA' reason for change:	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
Data Entry Error		
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'TN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'TN'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '37421' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '37421'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'US'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 19:48:20
User entered '2'	System	12 Nov 2020 17:20:58
User entered '1'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '29/Oct/2020 10:54'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'USA-US128-2020-MRNA-1273-P301000005'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Mark'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'McKenzie'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '6035 SHALLOWFORD ROAD SUITE 109' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '6035 Shallowford Road suite 109'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'CHATTANOOGA' reason for change:	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
Data Entry Error		
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'TN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'TN'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '37421' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '37421'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'US'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 19:48:20
User entered '2'	System	12 Nov 2020 17:20:58
User entered '1'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:56:07
User entered '12/Nov/2020 09:56'	Erica Osmundsen (b) (4)	12 Nov 2020 14:56:58

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 17:20:58

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'USA-US128-2020-MRNA-1273-P301000005'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Yes (Y)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'No (N)'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'Mark'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:32:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 14:54:06
User entered 'McKenzie'	System	29 Oct 2020 14:53:47

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '6035 SHALLOWFORD ROAD SUITE 109' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '6035 Shallowford Road suite 109'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'CHATTANOOGA' reason for change:	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
Data Entry Error		
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered 'TN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'TN'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Nov 2020 19:48:20
User entered empty.	System	24 Nov 2020 19:48:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:12:00
User entered '37421' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 14:41:42
DataPoint Un-verified.	System	12 Nov 2020 17:20:58
User entered empty.	System	12 Nov 2020 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered '37421'	Erica Osmundsen (b) (4)	04 Nov 2020 20:48:45

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:32:59
User entered 'US'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 19:48:20
User entered '2'	System	12 Nov 2020 17:20:58
User entered '1'	System	29 Oct 2020 14:54:16

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered '24/Nov/2020 19:48'	(b) (4) System	24 Nov 2020 19:48:20

US3202310

Folder: SAE USA-US128-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:38

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)	16 Apr 2021 17:40:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:01:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:48:20