

US3202231 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:44:37

All time stamps listed in this document are displayed in GMT

US3202231

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Participant ID

US3202231

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

US3202231

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:14:38

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:14:38

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Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	HTN
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	OSTEOARTHRITIS LEFT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	VITAMIN B DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	PSORIASIS- GENERAL
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	PSORIATIC ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:39 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:39
Height (<i>xxx.x</i>)	157.1 cm
Weight (<i>xxx.x</i>)	63.9 kg
BMI (<i>xxx.x</i>)	25.89098 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:14:38

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Date of assessment (dd MMM yyyy) 17 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 1977

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:14:38

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:14:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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

What was the participant's randomization number? 186648

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:39
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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)	17 AUG 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 16:59
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:22 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 16:22

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	15:53 (24 HR)
Collection date and time (derived)	17 AUG 2020 15:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	17 AUG 2020 15:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:48

PC Open Date & Time

17 AUG 2020 16:42

PC Close Date & Time

17 AUG 2020 19:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	17 AUG 2020 23:54
PC Open Date & Time	17 AUG 2020 20:07
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

97.3 °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

18 AUG 2020 17:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

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

19 AUG 2020 15:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

98.4 °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

20 AUG 2020 19:10

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

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

21 AUG 2020 13:51

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

98.3 °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

22 AUG 2020 20:32

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

97.2 °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

23 AUG 2020 12:19

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 16:49

PC Open Date & Time

17 AUG 2020 16:42

PC Close Date & Time

17 AUG 2020 19:12

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

17 AUG 2020 23:56

PC Open Date & Time

17 AUG 2020 20:07

PC Close Date & Time

18 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 17:14

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

19 AUG 2020 15:08

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:13

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

21 AUG 2020 13:52

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

22 AUG 2020 20:32

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

23 AUG 2020 12:19

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 16:50
PC Open Date & Time	17 AUG 2020 16:42
PC Close Date & Time	17 AUG 2020 19:12

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 23:57
PC Open Date & Time	17 AUG 2020 20:07
PC Close Date & Time	18 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 17:18
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 2075

EAB) (1725)

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:09
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

54 of 2075

EAB) (1725)

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:13
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 13:53
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:33
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:20
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3202231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments LEFT MESSAGE

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments MESSAGE LEFT

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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)	14 SEP 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:10
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:42 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:42
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

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.

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

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

Treatment Date and Time (derived) 14 SEP 2020 11:59

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

US3202231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	11:28 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:28

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	14 SEP 2020 11:26
Nasopharyngeal Swab 2	No		

US3202231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:38

PC Open Date & Time

14 SEP 2020 12:19

PC Close Date & Time

14 SEP 2020 14:49

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 98.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 14 SEP 2020 21:53

PC Open Date & Time 14 SEP 2020 15:44

PC Close Date & Time 15 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

100.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 SEP 2020 15:47

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 15:47

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

99.3 °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

17 SEP 2020 19:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

98.8 °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

18 SEP 2020 21:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

98.8 °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

19 SEP 2020 19:37

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

97.5 °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

20 SEP 2020 12:31

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

14 SEP 2020 12:40

PC Open Date & Time

14 SEP 2020 12:19

PC Close Date & Time

14 SEP 2020 14:49

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:02

PC Open Date & Time

14 SEP 2020 15:44

PC Close Date & Time

15 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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)

10

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

15 SEP 2020 15:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

16 SEP 2020 15:48

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

17 SEP 2020 19:20

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

18 SEP 2020 21:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

19 SEP 2020 19:38

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

20 SEP 2020 12:32

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 12:41
PC Open Date & Time	14 SEP 2020 12:19
PC Close Date & Time	14 SEP 2020 14:49

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 22:05
PC Open Date & Time	14 SEP 2020 15:44
PC Close Date & Time	15 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 15:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:49
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:22
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 21:17
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:39
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 ☒

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:32
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:37

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:56
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3202231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	12:03 (24 HR)
Collection date and time (derived)	13 OCT 2020 12:03

US3202231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:14:38

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 13:22:54

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 12:21:55

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

02 DEC 2020 11:22:27

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

11 DEC 2020 16:47:36

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

16 DEC 2020 08:39:45

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

25 DEC 2020 20:46:03

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

30 DEC 2020 12:52:07

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

06 JAN 2021 09:45:36

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

13 JAN 2021 10:24:25

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

22 JAN 2021 13:02:20

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 <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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

11 FEB 2021 12:26:56

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 14:56:03

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

26 FEB 2021 17:07:02

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

06 MAR 2021 18:18:36

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

13 MAR 2021 18:18:36

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

19 MAR 2021 12:02:12

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

26 MAR 2021 12:29:43

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

02 APR 2021 08:33:00

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

11 APR 2021 09:54:08

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

15 APR 2021 21:59:41

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 13:37:42

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 20:05:43

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 320

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

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

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

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

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

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

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 404

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

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

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

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

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 411

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

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

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

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

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

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

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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°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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 446

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

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

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

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

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

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

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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="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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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06 FEB 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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13 FEB 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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20 FEB 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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23 FEB 2022 00:01

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27 FEB 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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06 MAR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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13 MAR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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20 MAR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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27 MAR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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10 APR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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13 APR 2022 00:01

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17 APR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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20 APR 2022 00:01

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24 APR 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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°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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3202231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:44:37

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		06 MAR 2021 18:17:45

US3202231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:47:43

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

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

Comments LVM
SUB CALLED BACK

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:47:43

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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

Visit date (dd MMM yyyy)	19 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
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US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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) _____

US3202231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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.

US3202231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	12:08 (24 HR)
Collection date and time (derived)	19 MAR 2021 12:08

US3202231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:20:49

Generated On: 09 Jun 2021 15:44:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202231

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:20:49

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202231

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

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

US3202231

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202231

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:37

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"/>

US3202231

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:44:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202231

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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

Visit date (dd MMM yyyy)	22 JAN 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
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US3202231

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3202231

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

11:51 (24 HR)

Collection date and time (derived)

22 JAN 2021 11:51

US3202231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	11:50
Collection Date and Time (derived)	22 JAN 2021 11:50

US3202231

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:11:30

Generated On: 09 Jun 2021 15:44:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:15:18

Generated On: 09 Jun 2021 15:44:37

AEID	USA-US128-2020-MRNA-1273-P30 1000006
Adverse event	EMBOLIC STROKE
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)	31 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)	31 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)	31 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:15:18

Generated On: 09 Jun 2021 15:44:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:15:18

Generated On: 09 Jun 2021 15:44:37

SUBJECT'S PCP CONTACTED
SITE ON 05NOV2020 TO NOTIFY
THAT SUBJECT HAD BEEN
HOSPITALIZED FOR MILD
EMBOLIC STROKE IN WICHITA,
KANSAS WHILE VISITING
FAMILY THERE. HE STATED
HE'D SEND RECORDS HE'D JUST
RECEIVED FROM HOSPITAL. I
CONTACTED SUBJECT AND SHE
FELT FULLY RECOVERED. SHE
AND HER HUSBAND WERE IN
THE CAR DRIVING BACK TO TN
FROM WICHITA AT THE TIME
OF CALL. SHE IS SUPPOSED TO
F/UP WITH CARDIOLOGIST TO
HAVE SENSOR IMPLANTED TO
MONITOR FOR POSSIBLE A-FIB
PER SUBJECT. I ALSO SENT
RELEASE TO THE HOSPITAL TO
REQUEST RECORDS. NOT YET
RECEIVED.--RECORDS NOTE
RIGHT SIDED PARATHESIA
RESOLVED AS DID SUBJECT
REPORT SO OUTCOME
UPDATED TO RESOLVED.
SUBJECT TESTED FOR
COVID-19 AT HOSPITAL VIA
NASOPHARYNGEAL SWAB
COLLECTED 03NOV2020.
DIAGNOSTIC TESTS AND
RESULTS/IMPRESSIONS: BRAIN
MRI W/O CONTRAST
01NOV2020-NONHEMORRHAGIC
, SMALL ACUTE SUBCORTICAL

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:15:18

Generated On: 09 Jun 2021 15:44:37

WHITE MATTER INFARCT LEFT
FRONTAL LOBE;
TRANSTHORACIC
ECHOCARDIOGRAM
02NOV2020-POSITIVE BUBBLE
STUDY, NO MASSES OR CLOTS;
CT PELVIS W/ CONTRAST
03NOV2020-NO EVIDENCE OF
DVT; ULTRASOUND DOPPLER
LOWER EXTREMITIES VENOUS
BILATERAL 02NOV2020-NO
EVIDENCE OF DVT IN
BILATERAL LOWER
EXTREMITIES; CT HEAD W/O
CONTRAST 31OCT2020-NO
ACUTE FINDINGS (NEGATIVE);
CT ANGIOGRAPHY HEAD AND
NECK 31OCT2020-NO ACUTE
FINDINGS; ABNORMAL LABS
OF NOTE-D-DIMER, QUANT
02NOV2020 WAS 939 NG/ML
(REF RANGE <500 NG/ML.

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

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

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

Yes ☒

No ☐

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

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication OTEZLA

Prophylaxis Yes ☒
No ☐

Indication PSORIATIC ARTHRITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication HYDROCHLORTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1988
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication TUMERIC

Prophylaxis Yes ☒
No ☐

Indication GENERAL SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication SUPER B COMPLEX

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication LUTEIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication FOLIC ACID

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1977	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	1) FEVER 2) PAIN
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	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)	15 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROPHYLAXIS/ STROKE
PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	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)		31 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication EMBOLIC STROKE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	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)	31 OCT 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"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

Name of Medication ALLEGRA (FEXOFENADINE)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:43:01

Generated On: 09 Jun 2021 15:44:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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"/>

US3202231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 15:44:37

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3202231

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:44:37

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:44:37

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 ☐

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

SAEID	USA-US128-2020-MRNA-1273-P301000006
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)	4

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

SAEID	USA-US128-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	09/NOV/2020 12:04
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

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

SAEID	USA-US128-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	13/NOV/2020 17:31
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

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

SAEID	USA-US128-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 15:43:02

Generated On: 09 Jun 2021 15:44:37

SAEID	USA-US128-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	19/FEB/2021 15:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202231 (Prod: WR-ClinSearch, LLC)

US3202231

Form: Participant Creation

Generated On: 09 Jun 2021 15:44:37

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:43:44
User entered 'US3202231'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:24:22

US3202231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:41

US3202231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:24:23

US3202231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:41

US3202231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'SCRN'	System	17 Aug 2020 20:32:41

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered (b) (6) 1943'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:24:24

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	24 Aug 2020 20:38:06
User entered '77' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 20:38:06
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 20:37:10
User entered '70'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'YEARS'	System	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '77'	System	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:20:35
Query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' answered with 'fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	15 Sep 2020 15:19:33
User opened query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicate 'Yes or No'. please review and update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:21:40
User entered 'Female (F)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'I'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 20:37:10

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Aug 2020'	System	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2020'	System	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:53

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:24:23

US3202231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'I'	System	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:44:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:07

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 03:54:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 03:54:47
Data point term sent to Coder	System	19 Sep 2020 03:54:25
User entered 'TUBAL LIGATION'	Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 1977'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 1977'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 1977'	System	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '1977'	System	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 1977'	System	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '1977'	System	19 Sep 2020 03:53:59

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:57:34
Data point term sent to Coder	System	14 Oct 2020 18:56:44
User entered 'HTN'	Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 1983'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 1983'	System	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '1983'	System	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:56:00

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS- GENERALIZED (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:51:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:47:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:47:23
Data point term sent to Coder	System	06 Nov 2020 20:46:28
Query 'Per DM CLR: Please specify the type of ARTHRITIS- GENERALIZED (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' answered with 'CLARIFIED WITH SUBJECT VIA PHONE AND UPDATED SOURCE AS WELL AS EDC WITH ADDITIONAL DETAIL' (Site from DM).	Erica Osmundsen (b) (4)	06 Nov 2020 20:46:26
Coding entries removed.	Erica Osmundsen (b) (4)	06 Nov 2020 20:46:05
User entered 'OSTEOARTHRITIS LEFT SHOULDER' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	06 Nov 2020 20:46:05

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS- GENERALIZED (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:14:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 22:46:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 22:46:24
Data point term sent to Coder	System	14 Oct 2020 19:05:12
Coding entries removed.	Teresa Deese (b) (4)	14 Oct 2020 19:04:54
User entered 'ARTHRITIS- generalized' reason for change: Data Entry Error	Teresa Deese (b) (4)	14 Oct 2020 19:04:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:58:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 18:58:37
Data point term sent to Coder	System	14 Oct 2020 18:57:47
User entered 'arthritis'	Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 2000'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 2000'	System	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2000'	System	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:57:01

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B complex deficiency, LLT: Unspecified vitamin B deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:59:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:59:39
Data point term sent to Coder	System	14 Oct 2020 18:58:50
User entered 'vitamin B deficiency'	Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 2000'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 2000'	System	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2000'	System	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 18:58:28

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 04:37:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 04:37:31
Data point term sent to Coder	System	14 Oct 2020 19:00:55
User entered 'psoriasis- general'	Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 2018'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 2018'	System	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2018'	System	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	14 Oct 2020 19:00:36

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Psoriatic arthropathies, PT: Psoriatic arthropathy, LLT: Psoriatic arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:49:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:49:22
Data point term sent to Coder	System	06 Nov 2020 20:48:30
User entered 'PSORIATIC ARTHRITIS'	Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 2018'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 2018'	System	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2018'	System	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	06 Nov 2020 20:47:31

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 17:04:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 17:04:33
Data point term sent to Coder	System	12 Nov 2020 17:02:56
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 2015'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 2015'	System	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '2015'	System	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	12 Nov 2020 17:02:03

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 17:04:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 17:04:35
Data point term sent to Coder	System	12 Nov 2020 17:03:59
User entered 'SEASONAL ALLERGIES'	Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'UN UNK 1958'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'Jan 1958'	System	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '1958'	System	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered empty.	System	12 Nov 2020 17:03:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '15:39'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '17 Aug 2020 15:39'	System	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '157.1' cm	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '63.9' kg	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered '25.89098'	System	07 Sep 2020 16:40:37
DataPoint set to visible.	System	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'kg/m2'	System	07 Sep 2020 16:40:37
DataPoint set to visible.	System	17 Aug 2020 20:32:59

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'bpm'	System	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'breaths/min'	System	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'mmHg'	System	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User entered 'mmHg'	System	07 Sep 2020 16:40:37

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13

US3202231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13

US3202231

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:59

US3202231

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:28:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:13:25
User entered '17 Aug 2020'	zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:59

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:29:27
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'bilateral' (Site from DM).	Teresa Deese (b) (4)	14 Oct 2020 18:39:26
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:32:27
User closed query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:07:31
Query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' answered with 'ADDED' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 03:54:09
User opened query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 07:24:40
User entered 'Surgically sterile (SURGICALLY STERILE)'	zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'un UNK 1977'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:37

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:00

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

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 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'I'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'I'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:51:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Plans on routinely going to places where people gather.'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:39:47

US3202231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:11

US3202231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:11

US3202231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:11

US3202231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'VISIT1'	System	17 Aug 2020 20:33:11

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:54:15

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:07:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:07:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:54:15
User entered '186648' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:54:15

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:54:15

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:01:29
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 21:33:24
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Sep 2020 21:33:00
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:38:36

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 21:33:00

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 21:33:00

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 21:33:00

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 21:33:00

US3202231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:37

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:05:22
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:43:27

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '15:39'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '17 Aug 2020 15:39'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '36.1' C	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '80'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'bpm'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'breaths/min'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '138'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '84'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '16:59'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '17 Aug 2020 16:59'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '36.9' C	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50
	(b) (4)	

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '77'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'bpm'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'breaths/min'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '124'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '81'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	07 Sep 2020 16:42:50

US3202231

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Sep 2020 16:42:54

US3202231

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:54

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '16:22'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '17 Aug 2020 16:22'	System	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'ONCE'	System	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:33:35

US3202231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:58

US3202231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:58

US3202231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '15:53'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:33:58

US3202231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '17 Aug 2020 15:53'	System	17 Aug 2020 20:33:58

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '17 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '15:50'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '17 Aug 2020 15:50'	System	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered empty.	System	17 Aug 2020 20:34:16

US3202231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Sep 2020 16:42:59

US3202231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	07 Sep 2020 16:42:59

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '935643bf-7cce-40b3-bd4a-f2f23af4c0a8'	System	17 Aug 2020 20:48:34
User entered 'Yes (Y)'	System	17 Aug 2020 20:48:34

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '935643bf-7cce-40b3-bd4a-f2f23af4c0a8' User entered '97.0'	System	17 Aug 2020 20:48:34
	System	17 Aug 2020 20:48:34

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '935643bf-7cce-40b3-bd4a-f2f23af4c0a8'	System	17 Aug 2020 20:48:34
User entered 'No (N)'	System	17 Aug 2020 20:48:34

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '935643bf-7cce-40b3-bd4a-f2f23af4c0a8'	System	17 Aug 2020 20:48:34
User entered '17 Aug 2020 16:48'	System	17 Aug 2020 20:48:34

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 16:42'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 19:12'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:52:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '302aba8c-7a7d-4f51-93ed-d024e7753524' User entered 'Yes (Y)'	System	18 Aug 2020 03:54:35
	System	18 Aug 2020 03:54:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:54:08', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '302aba8c-7a7d-4f51-93ed-d024e7753524' User entered '97.6'	System	18 Aug 2020 03:54:35
	System	18 Aug 2020 03:54:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:54:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '302aba8c-7a7d-4f51-93ed-d024e7753524'	System	18 Aug 2020 03:54:35
User entered 'No (N)'	System	18 Aug 2020 03:54:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:54:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '302aba8c-7a7d-4f51-93ed-d024e7753524' User entered '17 Aug 2020 23:54'	System	18 Aug 2020 03:54:35
	System	18 Aug 2020 03:54:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 20:07'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 2'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:12:10', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c114fae5-6324-4e58-a7d5-d3907f6e7727' User entered 'Yes (Y)'	System	18 Aug 2020 21:13:33
	System	18 Aug 2020 21:13:33

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:12:22', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c114fae5-6324-4e58-a7d5-d3907f6e7727' User entered '97.3'	System	18 Aug 2020 21:13:33
	System	18 Aug 2020 21:13:33

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:13:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c114fae5-6324-4e58-a7d5-d3907f6e7727'	System	18 Aug 2020 21:13:33
User entered 'No (N)'	System	18 Aug 2020 21:13:33

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:13:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c114fae5-6324-4e58-a7d5-d3907f6e7727' User entered '18 Aug 2020 17:13'	System	18 Aug 2020 21:13:33
	System	18 Aug 2020 21:13:33

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 3'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:07:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '824f2098-c3d2-494a-9ee2-b03b1715bbe4'	System	19 Aug 2020 19:07:56
User entered 'Yes (Y)'	System	19 Aug 2020 19:07:56

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:07:37', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '824f2098-c3d2-494a-9ee2-b03b1715bbe4' User entered '98.0'	System	19 Aug 2020 19:07:56
	System	19 Aug 2020 19:07:56

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:07:46', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '824f2098-c3d2-494a-9ee2-b03b1715bbe4'	System	19 Aug 2020 19:07:56
User entered 'No (N)'	System	19 Aug 2020 19:07:56

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:07:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '824f2098-c3d2-494a-9ee2-b03b1715bbe4' User entered '19 Aug 2020 15:07'	System	19 Aug 2020 19:07:56
	System	19 Aug 2020 19:07:56

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 4'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:09:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c5f82bc3-9fb2-4a45-b69a-da9d463d9b2a' User entered 'Yes (Y)'	System	20 Aug 2020 23:10:29
	System	20 Aug 2020 23:10:29

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c5f82bc3-9fb2-4a45-b69a-da9d463d9b2a' User entered '98.4'	System	20 Aug 2020 23:10:29
	System	20 Aug 2020 23:10:29

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:17', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c5f82bc3-9fb2-4a45-b69a-da9d463d9b2a'	System	20 Aug 2020 23:10:29
User entered 'No (N)'	System	20 Aug 2020 23:10:29

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c5f82bc3-9fb2-4a45-b69a-da9d463d9b2a' User entered '20 Aug 2020 19:10'	System	20 Aug 2020 23:10:29
	System	20 Aug 2020 23:10:29

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 5'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:51:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7890e8a6-3115-4acc-9090-cd597225caee' User entered 'Yes (Y)'	System	21 Aug 2020 17:52:02
	System	21 Aug 2020 17:52:02

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:51:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7890e8a6-3115-4acc-9090-cd597225caee' User entered '98.0'	System	21 Aug 2020 17:52:02
	System	21 Aug 2020 17:52:02

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:51:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7890e8a6-3115-4acc-9090-cd597225caee'	System	21 Aug 2020 17:52:02
User entered 'No (N)'	System	21 Aug 2020 17:52:02

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:51:58', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7890e8a6-3115-4acc-9090-cd597225caee' User entered '21 Aug 2020 13:51'	System	21 Aug 2020 17:52:02
	System	21 Aug 2020 17:52:02

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 6'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:31:49', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2744d472-6254-468e-ab94-8228893401b8'	System	23 Aug 2020 00:32:06
User entered 'Yes (Y)'	System	23 Aug 2020 00:32:06

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:31:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2744d472-6254-468e-ab94-8228893401b8' User entered '98.3'	System	23 Aug 2020 00:32:06
	System	23 Aug 2020 00:32:06

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:31:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2744d472-6254-468e-ab94-8228893401b8'	System	23 Aug 2020 00:32:06
User entered 'No (N)'	System	23 Aug 2020 00:32:06

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2744d472-6254-468e-ab94-8228893401b8'	System	23 Aug 2020 00:32:06
User entered '22 Aug 2020 20:32'	System	23 Aug 2020 00:32:06

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 7'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:18:43', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e2749af8-06ee-4b19-8cfc-d0afcd796903' User entered 'Yes (Y)'	System	23 Aug 2020 16:19:05
	System	23 Aug 2020 16:19:05

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:18:50', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e2749af8-06ee-4b19-8cfc-d0afcd796903' User entered '97.2'	System	23 Aug 2020 16:19:05
	System	23 Aug 2020 16:19:05

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:18:54', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e2749af8-06ee-4b19-8cfc-d0afcd796903'	System	23 Aug 2020 16:19:05
User entered 'No (N)'	System	23 Aug 2020 16:19:05

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e2749af8-06ee-4b19-8cfc-d0afcd796903' User entered '23 Aug 2020 12:19'	System	23 Aug 2020 16:19:05
	System	23 Aug 2020 16:19:05

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '82bada3f-4dd5-41c0-95b9-85d5606fd48c'	System	17 Aug 2020 20:49:16
User entered 'None (1)'	System	17 Aug 2020 20:49:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '82bada3f-4dd5-41c0-95b9-85d5606fd48c' User entered 'No (N)'	System	17 Aug 2020 20:49:16
	System	17 Aug 2020 20:49:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:48:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '82bada3f-4dd5-41c0-95b9-85d5606fd48c' User entered 'No (N)'	System	17 Aug 2020 20:49:16
	System	17 Aug 2020 20:49:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '82bada3f-4dd5-41c0-95b9-85d5606fd48c'	System	17 Aug 2020 20:49:16
User entered 'None (1)'	System	17 Aug 2020 20:49:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:13', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '82bada3f-4dd5-41c0-95b9-85d5606fd48c'	System	17 Aug 2020 20:49:16
User entered '17 Aug 2020 16:49'	System	17 Aug 2020 20:49:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 16:42'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 19:12'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:54:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a86f574d-3ffc-48c4-8507-916e5c42b266'	System	18 Aug 2020 03:56:16
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 03:56:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:55:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a86f574d-3ffc-48c4-8507-916e5c42b266'	System	18 Aug 2020 03:56:16
User entered 'No (N)'	System	18 Aug 2020 03:56:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:55:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a86f574d-3ffc-48c4-8507-916e5c42b266'	System	18 Aug 2020 03:56:16
User entered 'No (N)'	System	18 Aug 2020 03:56:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:55:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a86f574d-3ffc-48c4-8507-916e5c42b266'	System	18 Aug 2020 03:56:16
User entered 'None (1)'	System	18 Aug 2020 03:56:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a86f574d-3ffc-48c4-8507-916e5c42b266'	System	18 Aug 2020 03:56:16
User entered '17 Aug 2020 23:56'	System	18 Aug 2020 03:56:16

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Aug 2020 20:07'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 2'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:13:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c693c86a-67fe-481b-a812-a75a3d2d1bb1'	System	18 Aug 2020 21:14:25
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 21:14:25

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:13:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c693c86a-67fe-481b-a812-a75a3d2d1bb1' User entered 'No (N)'	System	18 Aug 2020 21:14:25
	System	18 Aug 2020 21:14:25

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:13:57', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c693c86a-67fe-481b-a812-a75a3d2d1bb1' User entered 'No (N)'	System	18 Aug 2020 21:14:25
	System	18 Aug 2020 21:14:25

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:14:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c693c86a-67fe-481b-a812-a75a3d2d1bb1' User entered 'None (1)'	System	18 Aug 2020 21:14:25
	System	18 Aug 2020 21:14:25

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:14:22', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c693c86a-67fe-481b-a812-a75a3d2d1bb1' User entered '18 Aug 2020 17:14'	System	18 Aug 2020 21:14:25
	System	18 Aug 2020 21:14:25

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 3'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a80db91d-8bfd-4db4-9a06-0828d9078549'	System	19 Aug 2020 19:08:31
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 19:08:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a80db91d-8bfd-4db4-9a06-0828d9078549' User entered 'No (N)'	System	19 Aug 2020 19:08:31
	System	19 Aug 2020 19:08:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:08', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a80db91d-8bfd-4db4-9a06-0828d9078549' User entered 'No (N)'	System	19 Aug 2020 19:08:31
	System	19 Aug 2020 19:08:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a80db91d-8bfd-4db4-9a06-0828d9078549'	System	19 Aug 2020 19:08:31
User entered 'None (1)'	System	19 Aug 2020 19:08:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a80db91d-8bfd-4db4-9a06-0828d9078549' User entered '19 Aug 2020 15:08'	System	19 Aug 2020 19:08:31
	System	19 Aug 2020 19:08:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 4'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1947f325-d989-4f66-8e40-808a32a7c6af'	System	20 Aug 2020 23:13:08
User entered 'None (1)'	System	20 Aug 2020 23:13:08

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:43', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1947f325-d989-4f66-8e40-808a32a7c6af'	System	20 Aug 2020 23:13:08
User entered 'No (N)'	System	20 Aug 2020 23:13:08

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:10:49', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1947f325-d989-4f66-8e40-808a32a7c6af'	System	20 Aug 2020 23:13:08
User entered 'No (N)'	System	20 Aug 2020 23:13:08

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:12:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1947f325-d989-4f66-8e40-808a32a7c6af'	System	20 Aug 2020 23:13:08
User entered 'None (1)'	System	20 Aug 2020 23:13:08

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1947f325-d989-4f66-8e40-808a32a7c6af' User entered '20 Aug 2020 19:13'	System	20 Aug 2020 23:13:08
	System	20 Aug 2020 23:13:08

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 5'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:51:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ef10cd16-d9e8-4b0a-b287-bc864c2428dd'	System	21 Aug 2020 17:53:03
User entered 'None (1)'	System	21 Aug 2020 17:53:03

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:52:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ef10cd16-d9e8-4b0a-b287-bc864c2428dd' User entered 'No (N)'	System	21 Aug 2020 17:53:03
	System	21 Aug 2020 17:53:03

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:52:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ef10cd16-d9e8-4b0a-b287-bc864c2428dd' User entered 'No (N)'	System	21 Aug 2020 17:53:03
	System	21 Aug 2020 17:53:03

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:52:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ef10cd16-d9e8-4b0a-b287-bc864c2428dd'	System	21 Aug 2020 17:53:03
User entered 'None (1)'	System	21 Aug 2020 17:53:03

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:52:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ef10cd16-d9e8-4b0a-b287-bc864c2428dd' User entered '21 Aug 2020 13:52'	System	21 Aug 2020 17:53:03
	System	21 Aug 2020 17:53:03

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 6'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6773e4a1-3140-4602-a00a-91e2d7b0a2e6' User entered 'None (1)'	System	23 Aug 2020 00:32:47
	System	23 Aug 2020 00:32:47

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6773e4a1-3140-4602-a00a-91e2d7b0a2e6' User entered 'No (N)'	System	23 Aug 2020 00:32:47
	System	23 Aug 2020 00:32:47

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6773e4a1-3140-4602-a00a-91e2d7b0a2e6' User entered 'No (N)'	System	23 Aug 2020 00:32:47
	System	23 Aug 2020 00:32:47

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6773e4a1-3140-4602-a00a-91e2d7b0a2e6' User entered 'None (1)'	System	23 Aug 2020 00:32:47
	System	23 Aug 2020 00:32:47

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6773e4a1-3140-4602-a00a-91e2d7b0a2e6' User entered '22 Aug 2020 20:32'	System	23 Aug 2020 00:32:47
	System	23 Aug 2020 00:32:47

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 7'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b1cd21c0-4841-4d23-9624-5adc868b20e3'	System	23 Aug 2020 16:19:31
User entered 'None (1)'	System	23 Aug 2020 16:19:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b1cd21c0-4841-4d23-9624-5adc868b20e3'	System	23 Aug 2020 16:19:31
User entered 'No (N)'	System	23 Aug 2020 16:19:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b1cd21c0-4841-4d23-9624-5adc868b20e3' User entered 'No (N)'	System	23 Aug 2020 16:19:31
	System	23 Aug 2020 16:19:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:18', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b1cd21c0-4841-4d23-9624-5adc868b20e3'	System	23 Aug 2020 16:19:31
User entered 'None (1)'	System	23 Aug 2020 16:19:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b1cd21c0-4841-4d23-9624-5adc868b20e3' User entered '23 Aug 2020 12:19'	System	23 Aug 2020 16:19:31
	System	23 Aug 2020 16:19:31

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered 'None (0)'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:39', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered 'None (0)'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered 'None (0)'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:47', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932' User entered 'None (0)'	System	17 Aug 2020 20:50:13
	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:54', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932' User entered 'None (0)'	System	17 Aug 2020 20:50:13
	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:49:57', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered 'None (0)'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:50:03', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered 'No (N)'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T16:50:08', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'f97e80ae-0d4d-4761-a8de-4a9537442932'	System	17 Aug 2020 20:50:13
User entered '17 Aug 2020 16:50'	System	17 Aug 2020 20:50:13

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '17 Aug 2020 16:42'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '17 Aug 2020 19:12'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:19', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:56:57', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'None (0)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:57:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered 'No (N)'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-17T23:57:18', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '05d44dad-4e89-4d95-88fd-52d2ce857aee' User entered '17 Aug 2020 23:57'	System	18 Aug 2020 03:57:21
	System	18 Aug 2020 03:57:21

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '17 Aug 2020 20:07'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 2'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:14:31', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered 'None (0)'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363'	System	18 Aug 2020 21:18:33
User entered 'No interference with activity (1)'	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered 'None (0)'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:19', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered 'None (0)'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:23', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered 'None (0)'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered 'None (0)'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:17:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363'	System	18 Aug 2020 21:18:33
User entered 'No (N)'	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-18T17:18:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '278a5c28-668f-4c09-8308-3c34316ff363' User entered '18 Aug 2020 17:18'	System	18 Aug 2020 21:18:33
	System	18 Aug 2020 21:18:33

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 3'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:37', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2'	System	19 Aug 2020 19:09:18
User entered 'None (0)'	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2'	System	19 Aug 2020 19:09:18
User entered 'None (0)'	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:45', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2'	System	19 Aug 2020 19:09:18
User entered 'None (0)'	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2' User entered 'None (0)'	System	19 Aug 2020 19:09:18
	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2' User entered 'None (0)'	System	19 Aug 2020 19:09:18
	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:08:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2' User entered 'None (0)'	System	19 Aug 2020 19:09:18
	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:09:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2'	System	19 Aug 2020 19:09:18
User entered 'No (N)'	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-19T15:09:13', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '9f50d2c3-7925-4282-992f-6616c4bd97d2'	System	19 Aug 2020 19:09:18
User entered '19 Aug 2020 15:09'	System	19 Aug 2020 19:09:18

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 4'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:13', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:18', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:24', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'None (0)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:38', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered 'No (N)'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-20T19:13:51', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3054c990-f5b7-4e6a-bd1e-9fc10f5a427a' User entered '20 Aug 2020 19:13'	System	20 Aug 2020 23:13:53
	System	20 Aug 2020 23:13:53

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 5'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:15', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:19', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:22', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'None (0)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered 'No (N)'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-21T13:53:46', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '0e1858c4-24ca-4ec2-9f7e-844db372fe8e' User entered '21 Aug 2020 13:53'	System	21 Aug 2020 17:53:48
	System	21 Aug 2020 17:53:48

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 6'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:32:55', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:10', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:19', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:31', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'None (0)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered 'No (N)'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-22T20:33:51', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'd62cec8b-5d7a-41d4-b5d8-dd37f7de5718' User entered '22 Aug 2020 20:33'	System	23 Aug 2020 00:33:54
	System	23 Aug 2020 00:33:54

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 7'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82' User entered 'None (0)'	System	23 Aug 2020 16:20:17
	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:38', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82' User entered 'None (0)'	System	23 Aug 2020 16:20:17
	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82' User entered 'None (0)'	System	23 Aug 2020 16:20:17
	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:46', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82' User entered 'None (0)'	System	23 Aug 2020 16:20:17
	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:49', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82' User entered 'None (0)'	System	23 Aug 2020 16:20:17
	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82'	System	23 Aug 2020 16:20:17
User entered 'None (0)'	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:19:55', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82'	System	23 Aug 2020 16:20:17
User entered 'No (N)'	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-08-23T12:20:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '009f83eb-5258-4db6-bd08-97cd14661b82'	System	23 Aug 2020 16:20:17
User entered '23 Aug 2020 12:20'	System	23 Aug 2020 16:20:17

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:33:35

US3202231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:15
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:11

US3202231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '24 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:11

US3202231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:11

US3202231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'LEFT MESSAGE'	Erica Osmundsen (b) (4)	19 Sep 2020 03:57:11

US3202231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:01

US3202231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	14 Sep 2020 16:13:01

US3202231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:35

US3202231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '31 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:35

US3202231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:35

US3202231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'MESSAGE LEFT'	Erica Osmundsen (b) (4)	19 Sep 2020 03:57:35

US3202231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:07

US3202231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	14 Sep 2020 16:13:07

US3202231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:52

US3202231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:44
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'OUT OF WINDOW' (Site from System).	Erica Osmundsen (b) (4)	19 Sep 2020 03:58:09
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Sep 2020 03:57:52
User entered '4 Sep 2020'	Erica Osmundsen (b) (4)	19 Sep 2020 03:57:52

US3202231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:52

US3202231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 03:57:52

US3202231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:15

US3202231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	14 Sep 2020 16:13:15

US3202231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:25

US3202231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:25

US3202231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:25

US3202231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'VISIT2'	System	14 Sep 2020 16:13:25

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '11:10'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '14 Sep 2020 11:10'	System	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '68'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'bpm'	System	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '18'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'breaths/min'	System	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '121'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '76'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:06:36

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '12:42'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '14 Sep 2020 12:42'	System	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '71'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'bpm'	System	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '12'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'breaths/min'	System	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '114'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '79'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:07:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:34

US3202231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:13:34

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '11:59'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '14 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'ONCE'	System	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:14:00

US3202231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '11:28'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '14 Sep 2020 11:28'	System	14 Sep 2020 16:14:32

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '11:26'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '14 Sep 2020 11:26'	System	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered empty.	System	14 Sep 2020 16:14:43

US3202231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 16:14:07

US3202231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '1'	System	14 Sep 2020 16:14:07

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:38:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4bf9363c-c2c2-4a87-ad5b-65a1a70cc818' User entered 'Yes (Y)'	System	14 Sep 2020 16:38:54
	System	14 Sep 2020 16:38:54

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:38:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4bf9363c-c2c2-4a87-ad5b-65a1a70cc818' User entered '98.2'	System	14 Sep 2020 16:38:54
	System	14 Sep 2020 16:38:54

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:38:42', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4bf9363c-c2c2-4a87-ad5b-65a1a70cc818'	System	14 Sep 2020 16:38:54
User entered 'No (N)'	System	14 Sep 2020 16:38:54

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:38:51', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4bf9363c-c2c2-4a87-ad5b-65a1a70cc818' User entered '14 Sep 2020 12:38'	System	14 Sep 2020 16:38:54
	System	14 Sep 2020 16:38:54

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 12:19'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 14:49'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:50:57', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af' User entered 'Yes (Y)'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:51:17', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af' User entered '98.8'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:51:25', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af' User entered 'Yes (Y)'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted. She took Tylenol for low grade fever' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:22:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lilian Nukuna (b) (4)	21 Sep 2020 17:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:53:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af'	(b) (4)	
User entered '1'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:53:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af' User entered '0'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:53:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '365d6dec-ceb2-4194-869a-d09ee3b3d6af' User entered '14 Sep 2020 21:53'	System	15 Sep 2020 01:53:27
	System	15 Sep 2020 01:53:27

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 15:44'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 2'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:46:22', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54'	System	15 Sep 2020 19:47:09
User entered 'Yes (Y)'	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:46:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54' User entered '100.4'	System	15 Sep 2020 19:47:09
	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:46:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54'	System	15 Sep 2020 19:47:09
User entered 'Yes (Y)'	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User closed query 'Per CDM: Response noted however it appears updates are incomplete. Kindly reconcile with the concomitant medication eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:22:46
Query 'Per CDM: Response noted however it appears updates are incomplete. Kindly reconcile with the concomitant medication eCRF and update as appropriate.' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	06 Nov 2020 20:49:08
User opened query 'Per CDM: Response noted however it appears updates are incomplete. Kindly reconcile with the concomitant medication eCRF and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 21:40:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 21:37:20
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject took Tylenol for low grade fever' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 17:28:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 19:47:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:46:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54'	System	15 Sep 2020 19:47:09
User entered '1'	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:46:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54' User entered '0'	System	15 Sep 2020 19:47:09
	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:47:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadcbf85-0ac8-4f1f-afb2-d25e645cfc54'	System	15 Sep 2020 19:47:09
User entered '15 Sep 2020 15:47'	System	15 Sep 2020 19:47:09

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 3'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d3f5b0e-7a79-4314-b627-ef4228717b6a' User entered 'Yes (Y)'	System	16 Sep 2020 19:47:40
	System	16 Sep 2020 19:47:40

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d3f5b0e-7a79-4314-b627-ef4228717b6a' User entered '99.4'	System	16 Sep 2020 19:47:40
	System	16 Sep 2020 19:47:40

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:25', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d3f5b0e-7a79-4314-b627-ef4228717b6a'	System	16 Sep 2020 19:47:40
User entered 'No (N)'	System	16 Sep 2020 19:47:40

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:38', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d3f5b0e-7a79-4314-b627-ef4228717b6a' User entered '16 Sep 2020 15:47'	System	16 Sep 2020 19:47:40
	System	16 Sep 2020 19:47:40

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 4'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:18:22', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75c99add-9d13-4c50-8b13-d97dbeb91611' User entered 'Yes (Y)'	System	17 Sep 2020 23:18:45
	System	17 Sep 2020 23:18:45

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:18:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75c99add-9d13-4c50-8b13-d97dbeb91611' User entered '99.3'	System	17 Sep 2020 23:18:45
	System	17 Sep 2020 23:18:45

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:18:35', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75c99add-9d13-4c50-8b13-d97dbeb91611'	System	17 Sep 2020 23:18:45
User entered 'No (N)'	System	17 Sep 2020 23:18:45

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:18:43', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75c99add-9d13-4c50-8b13-d97dbeb91611' User entered '17 Sep 2020 19:18'	System	17 Sep 2020 23:18:45
	System	17 Sep 2020 23:18:45

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 5'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:15:50', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2476dfb1-4f64-4e0a-8201-52682794d8f8' User entered 'Yes (Y)'	System	19 Sep 2020 01:16:12
	System	19 Sep 2020 01:16:12

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:15:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2476dfb1-4f64-4e0a-8201-52682794d8f8' User entered '98.8'	System	19 Sep 2020 01:16:12
	System	19 Sep 2020 01:16:12

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2476dfb1-4f64-4e0a-8201-52682794d8f8'	System	19 Sep 2020 01:16:12
User entered 'No (N)'	System	19 Sep 2020 01:16:12

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2476dfb1-4f64-4e0a-8201-52682794d8f8'	System	19 Sep 2020 01:16:12
User entered '18 Sep 2020 21:16'	System	19 Sep 2020 01:16:12

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 6'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:37:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2b3be807-98ce-439d-b3d4-9ff9a980dcb1' User entered 'Yes (Y)'	System	19 Sep 2020 23:37:55
	System	19 Sep 2020 23:37:55

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:37:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2b3be807-98ce-439d-b3d4-9ff9a980dcb1' User entered '98.8'	System	19 Sep 2020 23:37:55
	System	19 Sep 2020 23:37:55

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:37:47', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2b3be807-98ce-439d-b3d4-9ff9a980dcb1'	System	19 Sep 2020 23:37:55
User entered 'No (N)'	System	19 Sep 2020 23:37:55

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:37:53', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2b3be807-98ce-439d-b3d4-9ff9a980dcb1' User entered '19 Sep 2020 19:37'	System	19 Sep 2020 23:37:55
	System	19 Sep 2020 23:37:55

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 7'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b28d5af0-e8e1-4ea2-995a-aab730461ad4' User entered 'Yes (Y)'	System	20 Sep 2020 16:31:33
	System	20 Sep 2020 16:31:33

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b28d5af0-e8e1-4ea2-995a-aab730461ad4' User entered '97.5'	System	20 Sep 2020 16:31:33
	System	20 Sep 2020 16:31:33

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b28d5af0-e8e1-4ea2-995a-aab730461ad4'	System	20 Sep 2020 16:31:33
User entered 'No (N)'	System	20 Sep 2020 16:31:33

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:28', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b28d5af0-e8e1-4ea2-995a-aab730461ad4' User entered '20 Sep 2020 12:31'	System	20 Sep 2020 16:31:33
	System	20 Sep 2020 16:31:33

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:39:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '168f3d0d-19e6-409a-a8cb-342e681c4aa7'	System	14 Sep 2020 16:40:36
User entered 'None (1)'	System	14 Sep 2020 16:40:36

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:39:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '168f3d0d-19e6-409a-a8cb-342e681c4aa7' User entered 'No (N)'	System	14 Sep 2020 16:40:36
	System	14 Sep 2020 16:40:36

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:39:33', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '168f3d0d-19e6-409a-a8cb-342e681c4aa7' User entered 'No (N)'	System	14 Sep 2020 16:40:36
	System	14 Sep 2020 16:40:36

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:39:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '168f3d0d-19e6-409a-a8cb-342e681c4aa7'	System	14 Sep 2020 16:40:36
User entered 'None (1)'	System	14 Sep 2020 16:40:36

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '168f3d0d-19e6-409a-a8cb-342e681c4aa7'	System	14 Sep 2020 16:40:36
User entered '14 Sep 2020 12:40'	System	14 Sep 2020 16:40:36

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 12:19'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 14:49'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:56:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6'	System	15 Sep 2020 02:02:48
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:58:13', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6' User entered 'No (N)'	System	15 Sep 2020 02:02:48
	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T21:58:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6'	System	15 Sep 2020 02:02:48
User entered 'Yes (Y)'	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:00:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6' User entered '5'	System	15 Sep 2020 02:02:48
	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:02:06', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6'	System	15 Sep 2020 02:02:48
User entered 'None (1)'	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:02:46', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a744f32c-68a9-4ded-95c5-6808922cefa6'	System	15 Sep 2020 02:02:48
User entered '14 Sep 2020 22:02'	System	15 Sep 2020 02:02:48

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 15:44'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 2'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:47:58', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8'	System	15 Sep 2020 19:50:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:48:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8'	System	15 Sep 2020 19:50:44
User entered 'No (N)'	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:48:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8' User entered 'Yes (Y)'	System	15 Sep 2020 19:50:44
	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:50:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8' User entered '10'	System	15 Sep 2020 19:50:44
	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:50:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8'	System	15 Sep 2020 19:50:44
User entered 'None (1)'	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:50:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'e80c1473-afad-4d6e-bf99-e379b00370d8'	System	15 Sep 2020 19:50:44
User entered '15 Sep 2020 15:50'	System	15 Sep 2020 19:50:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 3'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75441fe0-3a39-4c3b-8f97-601071ee9849'	System	16 Sep 2020 19:48:39
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 19:48:39

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:47:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75441fe0-3a39-4c3b-8f97-601071ee9849' User entered 'No (N)'	System	16 Sep 2020 19:48:39
	System	16 Sep 2020 19:48:39

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:17', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75441fe0-3a39-4c3b-8f97-601071ee9849'	System	16 Sep 2020 19:48:39
User entered 'No (N)'	System	16 Sep 2020 19:48:39

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75441fe0-3a39-4c3b-8f97-601071ee9849' User entered 'None (1)'	System	16 Sep 2020 19:48:39
	System	16 Sep 2020 19:48:39

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:37', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75441fe0-3a39-4c3b-8f97-601071ee9849' User entered '16 Sep 2020 15:48'	System	16 Sep 2020 19:48:39
	System	16 Sep 2020 19:48:39

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 4'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:23', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2535583f-42a9-40be-a456-9808fef8fe5e' User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 23:20:37
	System	17 Sep 2020 23:20:37

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:19:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2535583f-42a9-40be-a456-9808fef8fe5e' User entered 'No (N)'	System	17 Sep 2020 23:20:37
	System	17 Sep 2020 23:20:37

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:19:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2535583f-42a9-40be-a456-9808fef8fe5e' User entered 'No (N)'	System	17 Sep 2020 23:20:37
	System	17 Sep 2020 23:20:37

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:19:13', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2535583f-42a9-40be-a456-9808fef8fe5e' User entered 'None (1)'	System	17 Sep 2020 23:20:37
	System	17 Sep 2020 23:20:37

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '2535583f-42a9-40be-a456-9808fef8fe5e' User entered '17 Sep 2020 19:20'	System	17 Sep 2020 23:20:37
	System	17 Sep 2020 23:20:37

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 5'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8562adc9-a855-4f62-85b3-ab2b2410af47'	System	19 Sep 2020 01:16:44
User entered 'None (1)'	System	19 Sep 2020 01:16:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:18', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8562adc9-a855-4f62-85b3-ab2b2410af47'	System	19 Sep 2020 01:16:44
User entered 'No (N)'	System	19 Sep 2020 01:16:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:28', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8562adc9-a855-4f62-85b3-ab2b2410af47'	System	19 Sep 2020 01:16:44
User entered 'No (N)'	System	19 Sep 2020 01:16:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:35', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8562adc9-a855-4f62-85b3-ab2b2410af47'	System	19 Sep 2020 01:16:44
User entered 'None (1)'	System	19 Sep 2020 01:16:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:42', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8562adc9-a855-4f62-85b3-ab2b2410af47'	System	19 Sep 2020 01:16:44
User entered '18 Sep 2020 21:16'	System	19 Sep 2020 01:16:44

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 6'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:08', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b8a92ed4-792f-431a-8bff-5c59493414ac'	System	19 Sep 2020 23:38:35
User entered 'None (1)'	System	19 Sep 2020 23:38:35

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b8a92ed4-792f-431a-8bff-5c59493414ac'	System	19 Sep 2020 23:38:35
User entered 'No (N)'	System	19 Sep 2020 23:38:35

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:15', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b8a92ed4-792f-431a-8bff-5c59493414ac'	System	19 Sep 2020 23:38:35
User entered 'No (N)'	System	19 Sep 2020 23:38:35

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b8a92ed4-792f-431a-8bff-5c59493414ac'	System	19 Sep 2020 23:38:35
User entered 'None (1)'	System	19 Sep 2020 23:38:35

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:31', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b8a92ed4-792f-431a-8bff-5c59493414ac'	System	19 Sep 2020 23:38:35
User entered '19 Sep 2020 19:38'	System	19 Sep 2020 23:38:35

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 7'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:46', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4df74069-8fd8-4699-884d-fad89c67c4d7'	System	20 Sep 2020 16:32:14
User entered 'None (1)'	System	20 Sep 2020 16:32:14

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:50', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4df74069-8fd8-4699-884d-fad89c67c4d7'	System	20 Sep 2020 16:32:14
User entered 'No (N)'	System	20 Sep 2020 16:32:14

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:31:54', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4df74069-8fd8-4699-884d-fad89c67c4d7'	System	20 Sep 2020 16:32:14
User entered 'No (N)'	System	20 Sep 2020 16:32:14

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:02', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4df74069-8fd8-4699-884d-fad89c67c4d7'	System	20 Sep 2020 16:32:14
User entered 'None (1)'	System	20 Sep 2020 16:32:14

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4df74069-8fd8-4699-884d-fad89c67c4d7'	System	20 Sep 2020 16:32:14
User entered '20 Sep 2020 12:32'	System	20 Sep 2020 16:32:14

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:48', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:55', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:40:57', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'None (0)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:41:02', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered 'No (N)'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T12:41:10', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '75ddb879-4cf7-491c-a087-e6afefec557d' User entered '14 Sep 2020 12:41'	System	14 Sep 2020 16:41:32
	System	14 Sep 2020 16:41:32

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 12:19'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 14:49'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:05:23', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered 'None (0)'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:04:25', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered 'None (0)'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:04:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered 'None (0)'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:04:35', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered 'None (0)'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:04:49', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered 'None (0)'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:04:58', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3'	System	15 Sep 2020 02:05:48
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:05:04', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3'	System	15 Sep 2020 02:05:48
User entered 'No (N)'	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-14T22:05:45', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a299a9a4-34c6-4925-b4f0-1b98572cdbe3' User entered '14 Sep 2020 22:05'	System	15 Sep 2020 02:05:48
	System	15 Sep 2020 02:05:48

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '14 Sep 2020 15:44'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 2'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:50:53', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c'	System	15 Sep 2020 19:52:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c'	System	15 Sep 2020 19:52:02
User entered 'Some interference with activity (2)'	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:08', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c' User entered 'Some interference with activity (2)'	System	15 Sep 2020 19:52:02
	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:15', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c'	System	15 Sep 2020 19:52:02
User entered 'No interference with activity (1)'	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:25', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c' User entered 'None (0)'	System	15 Sep 2020 19:52:02
	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:31', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c'	System	15 Sep 2020 19:52:02
User entered 'Some interference with activity not requiring medical attention (2)'	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:37', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c' User entered 'No (N)'	System	15 Sep 2020 19:52:02
	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-15T15:51:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '527301c4-6c50-4b48-a4c1-6575fbd2688c' User entered '15 Sep 2020 15:51'	System	15 Sep 2020 19:52:02
	System	15 Sep 2020 19:52:02

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 3'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:47', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:51', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:48:59', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:49:02', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:49:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'None (0)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:49:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered 'No (N)'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-16T15:49:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '10005a1b-8f9f-4c31-9239-07c7d2d658cb' User entered '16 Sep 2020 15:49'	System	16 Sep 2020 19:49:36
	System	16 Sep 2020 19:49:36

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 4'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:39', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'None (0)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'None (0)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:51', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'None (0)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:20:54', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'None (0)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:21:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da'	System	17 Sep 2020 23:22:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:21:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'None (0)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:21:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered 'No (N)'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-17T19:22:17', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '33f5c1ad-838d-4e5c-96b7-fa00a86805da' User entered '17 Sep 2020 19:22'	System	17 Sep 2020 23:22:18
	System	17 Sep 2020 23:22:18

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 5'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:49', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577'	System	19 Sep 2020 01:17:44
User entered 'None (0)'	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:16:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577' User entered 'None (0)'	System	19 Sep 2020 01:17:44
	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577' User entered 'None (0)'	System	19 Sep 2020 01:17:44
	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:02', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577' User entered 'None (0)'	System	19 Sep 2020 01:17:44
	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577' User entered 'None (0)'	System	19 Sep 2020 01:17:44
	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577' User entered 'None (0)'	System	19 Sep 2020 01:17:44
	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577'	System	19 Sep 2020 01:17:44
User entered 'No (N)'	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-18T21:17:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '19996195-550a-4178-8eee-178cd7597577'	System	19 Sep 2020 01:17:44
User entered '18 Sep 2020 21:17'	System	19 Sep 2020 01:17:44

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 6'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:38', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:45', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:50', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:53', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:38:55', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered 'None (0)'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:39:10', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4'	System	19 Sep 2020 23:39:30
User entered 'No (N)'	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-19T19:39:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'bc7303ac-ec55-4934-95cc-a0cb603f95a4' User entered '19 Sep 2020 19:39'	System	19 Sep 2020 23:39:30
	System	19 Sep 2020 23:39:30

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	14 Sep 2020 16:14:00
User entered 'Day 7'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:17', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:23', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:26', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:34', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'None (0)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered 'No (N)'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-09-20T12:32:52', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'adda2b5a-bb1f-4a91-a7d1-aaa2b09acc89' User entered '20 Sep 2020 12:32'	System	20 Sep 2020 16:32:53
	System	20 Sep 2020 16:32:53

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:14:00

US3202231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:14:00

US3202231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 17:31:16

US3202231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '21 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 17:31:16

US3202231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 17:31:16

US3202231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	Lilian Nukuna (b) (4)	21 Sep 2020 17:31:16

US3202231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 17:31:21

US3202231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	21 Sep 2020 17:31:21

US3202231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:19:06

US3202231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '28 Sep 2020'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 20:19:06

US3202231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:19:06

US3202231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	Lilian Nukuna (b) (4)	28 Sep 2020 20:19:06

US3202231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:19:11

US3202231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	28 Sep 2020 20:19:11

US3202231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:08:42

US3202231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '05 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:08:42

US3202231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:08:42

US3202231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:08:42

US3202231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:08:47

US3202231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	14 Oct 2020 19:08:47

US3202231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '13 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'VISIT3'	System	14 Oct 2020 19:09:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '13 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '11:56'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '13 Oct 2020 11:56'	System	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '37.1' C	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered empty.	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '66'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'bpm'	System	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '16'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'breaths/min'	System	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '122'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '70'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'mmHg'	System	14 Oct 2020 19:09:59

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20

US3202231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:13

US3202231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '13 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:13

US3202231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:39

US3202231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '13 Oct 2020'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:39

US3202231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered '12:03'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:39

US3202231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered '13 Oct 2020 12:03'	System	14 Oct 2020 19:10:39

US3202231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:14:39
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Oct 2020 19:10:45

US3202231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	14 Oct 2020 19:10:45

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 64'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 71'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 78'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07

US3202231

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:38:07
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered 'Day 92'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-17T13:22:01', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c6c1372b-6e71-411e-a775-3e3c10b3166b' User entered 'No (N)'	System	17 Nov 2020 18:22:56
	System	17 Nov 2020 18:22:56

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-17T13:22:11', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c6c1372b-6e71-411e-a775-3e3c10b3166b'	System	17 Nov 2020 18:22:56
User entered 'No (N)'	System	17 Nov 2020 18:22:56

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-17T13:22:54', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'c6c1372b-6e71-411e-a775-3e3c10b3166b' User entered '17 Nov 2020 13:22:54'	System	17 Nov 2020 18:22:56
	System	17 Nov 2020 18:22:56

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:33:35

US3202231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:39:23
Data entry locked.	System	17 Aug 2020 20:33:35
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:33:35

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-25T12:20:40', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a7698726-a76d-4b05-be32-31a3eb8af4d2' User entered 'No (N)'	System	25 Nov 2020 17:22:00
	System	25 Nov 2020 17:22:00

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-25T12:20:50', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a7698726-a76d-4b05-be32-31a3eb8af4d2'	System	25 Nov 2020 17:22:00
User entered 'No (N)'	System	25 Nov 2020 17:22:00

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-11-25T12:21:55', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'a7698726-a76d-4b05-be32-31a3eb8af4d2' User entered '25 Nov 2020 12:21:55'	System	25 Nov 2020 17:22:00
	System	25 Nov 2020 17:22:00

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-02T11:22:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'cf63b549-cb85-4374-852f-6cb0a6bdb072' User entered 'No (N)'	System	02 Dec 2020 16:22:30
	System	02 Dec 2020 16:22:30

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-02T11:22:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'cf63b549-cb85-4374-852f-6cb0a6bdb072'	System	02 Dec 2020 16:22:30
User entered 'No (N)'	System	02 Dec 2020 16:22:30

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-02T11:22:27', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'cf63b549-cb85-4374-852f-6cb0a6bdb072' User entered '02 Dec 2020 11:22:27'	System	02 Dec 2020 16:22:30
	System	02 Dec 2020 16:22:30

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-11T16:47:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '5ae94b2d-f93a-4a73-80db-3d35f0b71e88'	System	11 Dec 2020 21:47:38
User entered 'No (N)'	System	11 Dec 2020 21:47:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-11T16:47:19', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '5ae94b2d-f93a-4a73-80db-3d35f0b71e88'	System	11 Dec 2020 21:47:38
User entered 'No (N)'	System	11 Dec 2020 21:47:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-11T16:47:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '5ae94b2d-f93a-4a73-80db-3d35f0b71e88' User entered '11 Dec 2020 16:47:36'	System	11 Dec 2020 21:47:38
	System	11 Dec 2020 21:47:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-16T08:39:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '28c059de-4ccc-4436-abfe-1eca84b83b6d' User entered 'No (N)'	System	16 Dec 2020 13:39:52
	System	16 Dec 2020 13:39:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-16T08:34:21', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '28c059de-4ccc-4436-abfe-1eca84b83b6d' User entered 'No (N)'	System	16 Dec 2020 13:39:52
	System	16 Dec 2020 13:39:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-16T08:39:45', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '28c059de-4ccc-4436-abfe-1eca84b83b6d' User entered '16 Dec 2020 08:39:45'	System	16 Dec 2020 13:39:52
	System	16 Dec 2020 13:39:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-25T20:45:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7330c897-0bde-4cf8-beb7-f5f332a73f2a' User entered 'No (N)'	System	26 Dec 2020 01:46:05
	System	26 Dec 2020 01:46:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-25T20:45:45', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7330c897-0bde-4cf8-beb7-f5f332a73f2a' User entered 'No (N)'	System	26 Dec 2020 01:46:05
	System	26 Dec 2020 01:46:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-25T20:46:03', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '7330c897-0bde-4cf8-beb7-f5f332a73f2a' User entered '25 Dec 2020 20:46:03'	System	26 Dec 2020 01:46:05
	System	26 Dec 2020 01:46:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-30T12:51:44', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d76ab46-82ca-4dff-9732-363caf97332a' User entered 'No (N)'	System	30 Dec 2020 18:52:11
	System	30 Dec 2020 18:52:11

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-30T12:51:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d76ab46-82ca-4dff-9732-363caf97332a' User entered 'No (N)'	System	30 Dec 2020 18:52:11

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2020-12-30T12:52:07', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8d76ab46-82ca-4dff-9732-363caf97332a' User entered '30 Dec 2020 12:52:07'	System	30 Dec 2020 18:52:11
	System	30 Dec 2020 18:52:11

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-06T09:45:30', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6de9bae2-a56b-4f3d-b45f-43da7b7ca57e'	System	06 Jan 2021 14:45:42
User entered 'No (N)'	System	06 Jan 2021 14:45:42

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-06T09:45:32', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6de9bae2-a56b-4f3d-b45f-43da7b7ca57e'	System	06 Jan 2021 14:45:42
User entered 'No (N)'	System	06 Jan 2021 14:45:42

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-06T09:45:36', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '6de9bae2-a56b-4f3d-b45f-43da7b7ca57e' User entered '06 Jan 2021 09:45:36'	System	06 Jan 2021 14:45:42

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-13T10:24:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '16702fcd-4be9-4596-94b2-e0c9f13d6b42'	System	13 Jan 2021 15:24:28
User entered 'No (N)'	System	13 Jan 2021 15:24:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-13T10:24:14', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '16702fcd-4be9-4596-94b2-e0c9f13d6b42'	System	13 Jan 2021 15:24:28
User entered 'No (N)'	System	13 Jan 2021 15:24:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-13T10:24:25', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '16702fcd-4be9-4596-94b2-e0c9f13d6b42' User entered '13 Jan 2021 10:24:25'	System	13 Jan 2021 15:24:28
	System	13 Jan 2021 15:24:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-22T13:02:09', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b87ab491-41cd-4f48-855d-ccf0d3b55573' User entered 'No (N)'	System	22 Jan 2021 18:02:28
	System	22 Jan 2021 18:02:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you been exposed to someone with 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 (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-22T13:02:16', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b87ab491-41cd-4f48-855d-ccf0d3b55573'	System	22 Jan 2021 18:02:28
User entered 'No (N)'	System	22 Jan 2021 18:02:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3F2F2D7C-0F3D-4BE5-9DF3-64EEA0DA780D)', Time: '2021-01-22T13:02:20', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b87ab491-41cd-4f48-855d-ccf0d3b55573' User entered '22 Jan 2021 13:02:20'	System	22 Jan 2021 18:02:28
	System	22 Jan 2021 18:02:28

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-11T12:26:05', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ce67c444-7b25-4a69-a912-7f05d46e5275'	System	11 Feb 2021 17:27:12
User entered 'No (N)'	System	11 Feb 2021 17:27:12

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-11T12:26:12', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ce67c444-7b25-4a69-a912-7f05d46e5275' User entered 'No (N)'	System	11 Feb 2021 17:27:12
	System	11 Feb 2021 17:27:12

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-11T12:26:56', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'ce67c444-7b25-4a69-a912-7f05d46e5275'	System	11 Feb 2021 17:27:12
User entered '11 Feb 2021 12:26:56'	System	11 Feb 2021 17:27:12

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-17T14:55:29', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '965d55f4-c024-4f60-b988-60178ef6960d' User entered 'No (N)'	System	17 Feb 2021 19:56:05
	System	17 Feb 2021 19:56:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-17T14:55:41', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '965d55f4-c024-4f60-b988-60178ef6960d' User entered 'No (N)'	System	17 Feb 2021 19:56:05
	System	17 Feb 2021 19:56:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-17T14:56:03', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '965d55f4-c024-4f60-b988-60178ef6960d' User entered '17 Feb 2021 14:56:03'	System	17 Feb 2021 19:56:05
	System	17 Feb 2021 19:56:05

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-26T12:06:46-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4d3ceca0-7c51-4249-9b6e-00c255531ebc' User entered 'No (N)'	System	26 Feb 2021 17:16:15
	System	26 Feb 2021 17:16:15

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-26T12:06:51-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4d3ceca0-7c51-4249-9b6e-00c255531ebc'	System	26 Feb 2021 17:16:15
User entered 'No (N)'	System	26 Feb 2021 17:16:15

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-02-26T12:07:02-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '4d3ceca0-7c51-4249-9b6e-00c255531ebc' User entered '26 Feb 2021 17:07:02'	System	26 Feb 2021 17:16:15
	System	26 Feb 2021 17:16:15

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-06T18:18:03-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b73cab5b-5cde-4c5f-bfd3-b9619d9403d2'	System	06 Mar 2021 23:19:16
User entered 'No (N)'	System	06 Mar 2021 23:19:16

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-06T18:18:13-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b73cab5b-5cde-4c5f-bfd3-b9619d9403d2'	System	06 Mar 2021 23:19:16
User entered 'No (N)'	System	06 Mar 2021 23:19:16

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-06T18:18:36-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'b73cab5b-5cde-4c5f-bfd3-b9619d9403d2'	System	06 Mar 2021 23:19:16
User entered '06 Mar 2021 18:18:36'	System	06 Mar 2021 23:19:16

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-13T18:18:26-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadd16b1-2ba1-41d7-9fe3-08bebf318c2b'	System	13 Mar 2021 23:18:38
User entered 'No (N)'	System	13 Mar 2021 23:18:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-13T18:18:30-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadd16b1-2ba1-41d7-9fe3-08bebf318c2b'	System	13 Mar 2021 23:18:38
User entered 'No (N)'	System	13 Mar 2021 23:18:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-13T18:18:36-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eadd16b1-2ba1-41d7-9fe3-08bebf318c2b'	System	13 Mar 2021 23:18:38
User entered '13 Mar 2021 18:18:36'	System	13 Mar 2021 23:18:38

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-19T12:02:02-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '55331bb3-e8e4-43da-ba5f-2be5ec6a27f0'	System	19 Mar 2021 16:06:52
User entered 'No (N)'	System	19 Mar 2021 16:06:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-19T12:02:05-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '55331bb3-e8e4-43da-ba5f-2be5ec6a27f0'	System	19 Mar 2021 16:06:52
User entered 'No (N)'	System	19 Mar 2021 16:06:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-19T12:02:12-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '55331bb3-e8e4-43da-ba5f-2be5ec6a27f0'	System	19 Mar 2021 16:06:52
User entered '19 Mar 2021 12:02:12'	System	19 Mar 2021 16:06:52

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-26T12:29:00-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3bdf5edb-7f53-4530-84b8-adf160538273'	System	26 Mar 2021 16:31:40
User entered 'No (N)'	System	26 Mar 2021 16:31:40

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-26T12:29:13-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3bdf5edb-7f53-4530-84b8-adf160538273'	System	26 Mar 2021 16:31:40
User entered 'No (N)'	System	26 Mar 2021 16:31:40

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-26T12:29:43-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '3bdf5edb-7f53-4530-84b8-adf160538273' User entered '26 Mar 2021 12:29:43'	System	26 Mar 2021 16:31:40
	System	26 Mar 2021 16:31:40

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-02T08:32:43-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eb5ee2be-c18c-48f9-8c13-1aa8cf36a72d' User entered 'No (N)'	System	02 Apr 2021 12:33:26

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-02T08:32:51-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eb5ee2be-c18c-48f9-8c13-1aa8cf36a72d'	System	02 Apr 2021 12:33:26
User entered 'No (N)'	System	02 Apr 2021 12:33:26

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-02T08:33:00-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: 'eb5ee2be-c18c-48f9-8c13-1aa8cf36a72d'	System	02 Apr 2021 12:33:26
User entered '02 Apr 2021 08:33:00'	System	02 Apr 2021 12:33:26

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-11T09:53:59-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8aaca7c2-07fb-4c57-ae75-69ac14afaf10' User entered 'No (N)'	System	11 Apr 2021 13:54:13
	System	11 Apr 2021 13:54:13

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-11T09:54:02-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8aaca7c2-07fb-4c57-ae75-69ac14afaf10'	System	11 Apr 2021 13:54:13
User entered 'No (N)'	System	11 Apr 2021 13:54:13

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-11T09:54:08-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '8aaca7c2-07fb-4c57-ae75-69ac14afaf10'	System	11 Apr 2021 13:54:13
User entered '11 Apr 2021 09:54:08'	System	11 Apr 2021 13:54:13

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-15T21:59:20-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '36cda6ed-4dd4-4341-ae44-ba290c3ff31f' User entered 'No (N)'	System	16 Apr 2021 01:59:44
	System	16 Apr 2021 01:59:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-15T21:59:30-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '36cda6ed-4dd4-4341-ae44-ba290c3ff31f' User entered 'No (N)'	System	16 Apr 2021 01:59:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-15T21:59:41-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '36cda6ed-4dd4-4341-ae44-ba290c3ff31f' User entered '15 Apr 2021 21:59:41'	System	16 Apr 2021 01:59:44
	System	16 Apr 2021 01:59:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-21T13:37:10-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '86b647da-6a3e-4e7b-a443-0591b8d9d57d'	System	21 Apr 2021 17:37:44
User entered 'No (N)'	System	21 Apr 2021 17:37:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-21T13:37:21-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '86b647da-6a3e-4e7b-a443-0591b8d9d57d'	System	21 Apr 2021 17:37:44
User entered 'No (N)'	System	21 Apr 2021 17:37:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-04-21T13:37:42-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '86b647da-6a3e-4e7b-a443-0591b8d9d57d' User entered '21 Apr 2021 13:37:42'	System	21 Apr 2021 17:37:44
	System	21 Apr 2021 17:37:44

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-05-02T20:05:28-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '986fbeee-cce6-49e6-89ff-6ea3a051180d' User entered 'No (N)'	System	03 May 2021 00:05:45
	System	03 May 2021 00:05:45

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

Have you been exposed to someone with 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 (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-05-02T20:05:31-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '986fbeee-cce6-49e6-89ff-6ea3a051180d'	System	03 May 2021 00:05:45
User entered 'No (N)'	System	03 May 2021 00:05:45

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-05-02T20:05:43-04:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '986fbEEE-cce6-49e6-89ff-6ea3a051180d' User entered '02 May 2021 20:05:43'	System	03 May 2021 00:05:45
	System	03 May 2021 00:05:45

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:38:07

US3202231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:07
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:38:07

US3202231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-06T18:17:34-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1f2e8e94-7c20-4638-80d5-397a62ab121d'	System	06 Mar 2021 23:18:29
User entered 'No (N)'	System	06 Mar 2021 23:18:29

US3202231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:54:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1AEA4A0C-54E9-4B0F-933C-4E5B0BD8346C)', Time: '2021-03-06T18:17:45-05:00', User OID: 'PatientReportedOutcome (US3202231)', ODM File OID: '1f2e8e94-7c20-4638-80d5-397a62ab121d'	System	06 Mar 2021 23:18:29
User entered '06 Mar 2021 18:17:45'	System	06 Mar 2021 23:18:29

US3202231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:47:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:33:03

US3202231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:47:43
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:33:03

US3202231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:47:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	11 Nov 2020 17:18:46
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	10 Nov 2020 19:33:03

US3202231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:47:43
User entered 'LVM	(b) (4)	
Sub called back' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:18:46
User entered 'LVM'	(b) (4), (b) (6)	10 Nov 2020 19:33:03

US3202231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:47:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:18:52

US3202231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:01:20
User entered 'I'	System	11 Nov 2020 17:18:52

US3202231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:41:09

US3202231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:41:09

US3202231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:41:09

US3202231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:41:09

US3202231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:41:12

US3202231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User entered 'I'	System	11 Dec 2020 21:41:12

US3202231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:37:33
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:43:21
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 22JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 19:40:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:42:24

US3202231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 09:59:34
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:43:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 12:12:22
User entered '14 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:42:24

US3202231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	14 Jan 2021 16:42:24

US3202231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	Lilian Nukuna (b) (4)	14 Jan 2021 16:42:24

US3202231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Jan 2021 16:42:29

US3202231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User entered 'I'	System	14 Jan 2021 16:42:29

US3202231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 17:40:58

US3202231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:03:20
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:41:02
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Feb 2021 17:40:58
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:40:58

US3202231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 17:40:58

US3202231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) zackery harmon (b) (4)	21 Feb 2021 17:40:58
	(b) (4)	

US3202231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 17:41:07

US3202231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:25:10
User entered 'I'	System	21 Feb 2021 17:41:07

US3202231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:13

US3202231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '19 Mar 2021'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:13

US3202231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:13

US3202231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered 'VISIT4'	System	19 Mar 2021 16:52:13

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered empty.	System	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered empty.	System	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered empty.	System	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered empty.	System	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered empty.	System	01 Apr 2021 00:29:53

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30

US3202231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30

US3202231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:19

US3202231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:19

US3202231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:34

US3202231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '19 Mar 2021'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:34

US3202231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '12:08'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:34

US3202231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered '19 Mar 2021 12:08'	System	19 Mar 2021 16:52:34

US3202231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:52:24

US3202231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:30
User entered 'I'	System	19 Mar 2021 16:52:24

US3202231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:49
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 16:33:00

US3202231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:49
	(b) (4)	
User entered '14 Apr 2021'	Lilian Nukuna (b) (4)	14 Apr 2021 16:33:00

US3202231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	14 Apr 2021 16:33:00

US3202231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:49
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Apr 2021 16:33:00

US3202231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:49
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 16:33:05

US3202231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:37

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 16:33:05

US3202231

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:43:39

US3202231

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:43:39

US3202231

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:43:39

US3202231

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User entered 'UNBLND_DECIDE'	System	19 Feb 2021 20:43:39

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:55:59

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
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 16:55:59

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User entered empty.	System	19 Feb 2021 20:44:06

US3202231

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User entered empty.	System	19 Feb 2021 20:44:06

US3202231

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:47

US3202231

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:47

US3202231

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '11:51'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:47

US3202231

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User entered '22 Jan 2021 11:51'	System	19 Feb 2021 20:44:47

US3202231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:59

US3202231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:59

US3202231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:37

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '11:50'	(b) (4) Teresa Deese (b) (4)	19 Feb 2021 20:44:59

US3202231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:37

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:58:11
User entered '22 Jan 2021 11:50'	System	19 Feb 2021 20:44:59

US3202231

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:44:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:27:10
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:11:30
User closed query 'please review hypokalemia and elevated D-Dimer noted for clinical significance and possible AE capture. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:07:30
Query 'please review hypokalemia and elevated D-Dimer noted for clinical significance and possible AE capture. ' answered with 'REVIEWED BY DR. McKenzie, not CLINICALLY SIGNIFICANT HYPOKALEMIA (AND NOT TREATED), NOR D-DIMER' (Site from CRA).	Erica Osmundsen (b) (4)	12 Nov 2020 20:53:38
User opened query 'please review hypokalemia and elevated D-Dimer noted for clinical significance and possible AE capture. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:51:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:39:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	06 Nov 2020 20:15:26
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Oct 2020 15:54:59

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:04:31
User entered	System	09 Nov 2020 17:04:25
'USA-US128-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 17:04:25

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:07
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Embolic stroke, LLT: Embolic stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:30:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:30:22
Data point term sent to Coder	System	06 Nov 2020 20:29:00
User entered 'EMBOLIC STROKE'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:05
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:03
User entered 'No (N)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:58
User entered 'No (N)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:56
User entered '31 Oct 2020'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:55
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:51
User entered '31 Oct 2020'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:48
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:44
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:40
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:38
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:36
User entered 'I'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:34
User entered '31 Oct 2020'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:31
User entered '03 Nov 2020'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:29
User entered 'No (N)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:27
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:25
User entered '0'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:22
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:20
User entered '0'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:18
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:16
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:14
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:11
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:02:09
User entered 'I'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:28:35

US3202231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 17:32:55
User closed query 'per source = none, please verify ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:32:52
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure were Diagnostic procedures and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update this field as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:24:11
Query 'per source = none, please verify ' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	19 Feb 2021 20:46:34
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure were Diagnostic procedures and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update this field as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:46:30
User entered '0' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Feb 2021 20:46:20
User opened query 'per source = none, please verify ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:05:57
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 20:04:47
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure were Diagnostic procedures and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update this field as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 01:12:02
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:52:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'MULTIPLE IMAGING PROCEDURES HAVE BEEN ENTERED IN CON PROCEDURES ECRF PAGE' (Site from DM).	Erica Osmundsen (b) (4)	23 Nov 2020 21:43:13
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:11:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:02:08
User entered 'I'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:07:19
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	12 Nov 2020 20:44:04
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	12 Nov 2020 20:43:35
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Nov 2020 20:43:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Erica Osmundsen (b) (4)	12 Nov 2020 20:43:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:02:04
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

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 12:15:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:07:19
User entered empty; reason for change New Information	Erica Osmundsen (b) (4)	12 Nov 2020 20:44:04
User closed query 'Per source Right sided paresithesia ongoing, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:09:16
Query 'Per source Right sided paresithesia ongoing, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	12 Nov 2020 16:55:34
User entered 'MILD WEAKNESS IN RIGHT ARM PER OCCUPATIONAL THERAPIST--NOT NOTICABLE TO SUBJECT. MEDICAL RECORDS RECEIVED AND THESE NOTE RIGHT SIDED PARETHESIA ONGOING AT D/C. SUBJECT STATES NOT NOTICEABLE TO HER.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 16:55:29
User opened query 'Per source Right sided paresithesia ongoing, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:45:30
User entered 'MILD WEAKNESS IN RIGHT ARM PER OCCUPATIONAL THERAPIST--NOT NOTICABLE TO SUBJECT'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:18
User closed query 'Per CDM: Response noted however no updates have been made to the ConProc eCRF as per the previous query? Please review/ update accordingly. else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:14:30
Query 'Per CDM: Response noted however no updates have been made to the ConProc eCRF as per the previous query? Please review/ update accordingly. else clarify. Thank you' answered with 'there are no con proc to add. labs/tests are diagnostic not treatments & are not to be entered as con proc' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:44:48
User opened query 'Per CDM: Response noted however no updates have been made to the ConProc eCRF as per the previous query? Please review/ update accordingly. else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:26:45
User closed query 'Per DM CLR: SAE Narrative = ABNORMAL LABS OF NOTE-D-DIMER. However, this is not recorded in the ConProc eCRF (Blood Work-Up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:26:45
Query 'Per DM CLR: SAE Narrative = ABNORMAL LABS OF NOTE-D-DIMER. However, this is not recorded in the ConProc eCRF (Blood Work-Up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:46:54
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:28
User closed query 'Per DM CLR: SAE Narrative = SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB. Please review and confirm if this was performed. If yes, please ensure that this is captured in the ConProc eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:48:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = ABNORMAL LABS OF NOTE-D-DIMER. However, this is not recorded in the ConProc eCRF (Blood Work-Up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 01:10:39
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:44:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:43:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:43:48
User closed query 'Per DM CLR: SAE Narrative = RECORDS NOTE RIGHT SIDED PARATHESIA. Please review and confirm if this should be recorded as a separate AE. If yes, ensure that this is captured in the AE eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:33:29
Query 'Per DM CLR: SAE Narrative = SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB. Please review and confirm if this was performed. If yes, please ensure that this is captured in the ConProc eCRF. Otherwise, clarify.' answered with 'PENDING F/UP--WAS NOT DONE AS OF 10NOV2020' (Site from DM).	Erica Osmundsen (b) (4)	24 Nov 2020 23:03:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'DONE' (Site from Safety).	Erica Osmundsen (b) (4)	24 Nov 2020 23:01:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FROM HOSPITAL. I CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.--RECORDS NOTE RIGHT SIDED PARATHESIA RESOLVED AS DID SUBJECT REPORT SO OUTCOME UPDATED TO RESOLVED. SUBJECT TESTED FOR COVID-119 AT HOSPITAL VIA NASOPHARYNGEAL SWAB COLLECTED 03NOV2020. DIAGNOSTIC TESTS AND RESULTS/IMPRESSIONS: BRAIN MRI W/O CONTRAST 01NOV2020-NONHEMORRHAGIC, SMALL ACUTE SUBCORTICAL WHITE MATTER INFARCT LEFT FRONTAL LOBE; TRANSTHORACIC ECHOCARDIOGRAM 02NOV2020-POSITIVE BUBBLE STUDY, NO MASSES OR CLOTS; CT PELVIS W/ CONTRAST 03NOV2020-NO EVIDENCE OF DVT; ULTRASOUND DOPPLER LOWER EXTREMITIES VENOUS BILATERAL 02NOV2020-NO EVIDENCE OF DVT IN BILATERAL LOWER EXTREMITIES; CT HEAD W/O CONTRAST 31OCT2020-NO ACUTE FINDINGS (NEGATIVE); CT ANGIOGRAPHY HEAD AND NECK 31OCT2020-NO ACUTE FINDINGS; ABNORMAL LABS OF NOTE-D-DIMER, QUANT 02NOV2020 WAS 939 NG/ML (REF RANGE <500 NG/ML.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 23:00:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FORM HOSPITAL. I CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.--RECORDS NOTE RIGHT SIDED PARATHESIA RESOLVED AS DID SUBJECT REPORT SO OUTCOME UPDATED TO RESOLVED. SUBJECT TESTED FOR COVID-119 AT HOSPITAL VIA NASOPHARYNGEAL SWAB COLLECTED 03NOV2020. Diagnostic tests and results/impressions: BRAIN MRI W/O CONTRAST 01Nov2020-NONHEMORRHAGIC, SMALL ACUTE SUBCORTICAL WHITE MATTER INFARCT LEFT FRONTAL LOBE; Transthoracis Echocardiogram 02NOV2020-Positive bubble study, no masses or clots; CT Pelvis w/ Contrast 03NOV2020-No evidence of DVT; Ultrasound Doppler lower extremities venous bilateral 02NOV2020-No evidence of DVT in bilateral lower extremities; CT head w/o contrast 31OCT2020-no acute findings (negative); CT angiography head and neck 31OCT2020-no acute findings; abnormal labs of note-D-DIMER, Quant 02NOV2020 was 939 ng/mL (ref range <500 ng/mL.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 23:00:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FROM HOSPITAL. I CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.--RECORDS NOTE RIGHT SIDED PARATHESIA RESOLVED AS DID SUBJECT REPORT SO OUTCOME UPDATED TO RESOLVED. SUBJECT TESTED FOR COVID-119 AT HOSPITAL VIA NASOPHARYNGEAL SWAB COLLECTED 03NOV2020. Brain MRI w/o contrast Impression: NONHEMORRHAGIC, SMALL ACUTE SUBCORTICAL WHITE MATTER INFARCT LEFT FRONTAL LOBE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	24 Nov 2020 21:47:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'DONE' (Site from Safety).	Erica Osmundsen (b) (4)	24 Nov 2020 21:42:09
Query 'Per DM CLR: SAE Narrative = RECORDS NOTE RIGHT SIDED PARATHESIA. Please review and confirm if this should be recorded as a separate AE. If yes, ensure that this is captured in the AE eCRF as appropriate. Otherwise, clarify. ' answered with 'THIS WAS A TEMPORARY SYMPTOM OF THE STROKE AND NOT A SEPARATE AE' (Site from DM).	Erica Osmundsen (b) (4)	24 Nov 2020 21:41:55
DataPoint Un-verified.	Erica Osmundsen (b) (4)	24 Nov 2020 21:41:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FORM HOSPITAL. I CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.--RECORDS NOTE RIGHT SIDED PARATHESIA RESOLVED AS DID SUBJECT REPORT SO OUTCOME UPDATED TO RESOLVED. SUBJECT TESTED FOR COVID-119 AT HOSPITAL VIA NASOPHARYNGEAL SWAB COLLECTED 03NOV2020. DIAGNOSTIC IMAGING TESTS ENTERED UNDER CONCOMITANT PROCEDURES. WILL UPDATE TO INCLUDE RESULTS AS WELL AS ABNORMAL AND RELEVANT LAB TESTING'	Erica Osmundsen (b) (4)	24 Nov 2020 21:41:27
reason for change: Data Entry Error		
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'done' (Site from Safety).	Erica Osmundsen (b) (4)	24 Nov 2020 21:11:37
User opened query 'Per DM CLR: SAE Narrative = RECORDS NOTE RIGHT SIDED PARATHESIA. Please review and confirm if this should be recorded as a separate AE. If yes, ensure that this is captured in the AE eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:11:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB. Please review and confirm if this was performed. If yes, please ensure that this is captured in the ConProc eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:11:07
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:58:36
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)	13 Nov 2020 13:58:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:58:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:07:19
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Nov 2020 20:44:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FORM HOSPITAL. I CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.--RECORDS NOTE RIGHT SIDED PARATHESIA RESOLVED AS DID SUBJECT REPORT SO OUTCOME UPDATED TO RESOLVED' reason for change: Data Entry Error DataPoint Verified.	Erica Osmundsen (b) (4)	12 Nov 2020 20:44:51
User entered 'SUBJECT'S PCP CONTACTED SITE ON 05NOV2020 TO NOTIFY THAT SUBJECT HAD BEEN HOSPITALIZED FOR MILD EMBOLIC STROKE IN WICHITA, KANSAS WHILE VISITING FAMILY THERE. HE STATED HE'D SEND RECORDS HE'D JUST RECEIVED FORM HOSPITAL. i CONTACTED SUBJECT AND SHE FELT FULLY RECOVERED. SHE AND HER HUSBAND WERE IN THE CAR DRIVING BACK TO TN FROM WICHITA AT THE TIME OF CALL. SHE IS SUPPOSED TO F/UP WITH CARDIOLOGIST TO HAVE SENSOR IMPLANTED TO MONITOR FOR POSSIBLE A-FIB PER SUBJECT. I ALSO SENT RELEASE TO THE HOSPITAL TO REQUEST RECORDS. NOT YET RECEIVED.'	Erica Osmundsen (b) (4)	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:28:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 20:28:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:27:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 08:28:56
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'no Rx reported' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:39:18
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:07:15
User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on dairy dose 2 day 1& 2 and reply is noted as subject took Tylenol for low grade fever, Kindly update the concomitant medication accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:38:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on dairy dose 2 day 1& 2 and reply is noted as subject took Tylenol for low grade fever, Kindly update the concomitant medication accordingly. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:53
User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on dairy dose 2 day 1& 2 and reply is noted as subject took Tylenol for low grade fever, Kindly update the concomitant medication accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:16:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:40:59

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: SELECTIVE IMMUNOSUPPRESSANTS, PRODUCT: APREMILAST, PRODUCTSYNONYM: OTEZLA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:46:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:46:38
Data point term sent to Coder	System	14 Oct 2020 18:46:05
User entered 'Otezla'	Teresa Deese (b) (4) (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'psoriatic arthritis'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '30'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2018'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:45:41

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 21:10:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:10:21
Data point term sent to Coder	System	14 Oct 2020 18:47:09
User entered 'hydrochlorthiazide'	Teresa Deese (b) (4) (b) (4) (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'HTN'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '25'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 1988'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:46:37

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:49:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:49:49
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:49:14
User entered 'tumeric'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:30:52
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:45:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:45:15
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:00:18
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'general supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '100'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2018'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:48:51

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:51:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:51:41
Data point term sent to Coder	System	14 Oct 2020 18:50:19
User entered 'vitamin D'	Teresa Deese (b) (4) (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 08:00:24
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:39:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Feb 2021 20:39:38
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 07:33:51
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'general supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:44:09
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:46:13
User entered '1000' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:45:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:51:06
User entered '100'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:46:07
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:26:15
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	06 Nov 2020 20:32:22
User entered 'IU (IU)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	06 Nov 2020 20:32:17
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:30:14
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2018'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:49:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:53:36
Data point term sent to Coder	System	14 Oct 2020 18:52:25
User entered 'super B complex'	Teresa Deese (b) (4) (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:31:26
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:49:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:49:34
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:00:34
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:37:59
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components. ' answered with 'BRAND NAME IS REPORTED IN THE NAME OF COMBINATION DRUG PER CRF GUIDELINES' (Site from DM).	Erica Osmundsen (b) (4)	06 Nov 2020 20:32:59
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:30:33
User entered '50'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'ug (ug)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2000'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:51:40

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL, PRODUCTSYNONYM: LUTEIN [XANTOFYL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 18:54:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:54:31
Data point term sent to Coder	System	14 Oct 2020 18:53:30
User entered 'lutein'	Teresa Deese (b) (4) (b) (4) (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '20'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2018'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:53:11

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:55:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:55:42
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:54:34
User entered 'fish oil'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:31:36
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:50:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:50:03
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:00:51
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '1000'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2010'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:53:50

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:55:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:55:42
Data point term sent to Coder	System	14 Oct 2020 18:54:37
User entered 'folic acid'	Teresa Deese (b) (4) (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:31:44
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:50:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:50:24
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 08:01:00
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'supplement'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0.4' reason for change: Data Entry Error	Teresa Deese (b) (4)	05 Mar 2021 19:50:50
User entered '12'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 1977'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:54:29

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:53:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:53:25
Data point term sent to Coder	System	06 Nov 2020 20:52:35
Coding entries removed.	Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:32:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:32:21
Data point term sent to Coder	System	06 Nov 2020 20:32:05
User entered 'TYLENOL'	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 08:28:15
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'this was for a solicited event. Prophylaxis?' (Site from DM).	Teresa Deese (b) (4)	19 Feb 2021 20:40:56
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 07:34:22
User entered '1) FEVER 2) PAIN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User entered 'FEVER/PAIN'	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '500'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'mg (mg)'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'as needed (PRN)'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Oral (ORAL)'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered empty.	(b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User entered '18 Aug 2020'	(b) (4)	
	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	06 Nov 2020 20:51:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User entered empty.	System	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User entered empty.	System	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:23:26
User entered empty.	System	06 Nov 2020 20:31:17

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:10:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:10:22
Data point term sent to Coder	System	06 Nov 2020 20:43:22
User entered 'ASPIRIN'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:06:16
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:05
User entered 'CARDIOVASCULAR PROPHYLAXIS/ STROKE PREVENTION'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:07:07
User entered '81'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:47
User entered 'mg (mg)'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:48
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:50
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:56
User entered empty.	Erica Osmundsen (b) (4) 	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:53
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:57
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:15:58
User entered '31 Oct 2020'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:00
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:02
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:05
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:06
User entered 'No (N)'	Erica Osmundsen (b) (4) 	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:42:28

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:16:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:46:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:46:22
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 20:45:24
User entered 'CRESTOR'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:16:24
User entered 'EMBOLIC STROKE'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 19:30:18
User closed query 'source = 20, please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:30:16
Query 'source = 20, please verify' answered with 'UPDATED PER SOURCE' (Site from CRA).	Erica Osmundsen (b) (4)	12 Nov 2020 16:56:18
User entered '20' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Nov 2020 16:56:13
User opened query 'source = 20, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:20:23
User entered '10'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:24
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:48
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:31
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:33
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:34
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:36
User entered '31 Oct 2020'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:39
User entered '0'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:44:33
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'no a stop date should not be recorded' (Site from DM).	Teresa Deese (b) (4)	05 Mar 2021 19:51:38
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:11:41
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:41
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:43
User entered empty.	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:20:44
User entered 'No (N)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:45:21

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 17:02:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 17:02:32
Data point term sent to Coder	System	12 Nov 2020 17:01:55
User entered 'MELATONIN'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:40
User entered 'No (N)'	Erica Osmundsen (b) (4) 	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:42
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:51
User entered '5'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:53
User entered 'mg (mg)'	Erica Osmundsen (b) (4) 	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:05
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:56
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:03
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:01
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:59
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:08
User entered 'UN UNK 2015'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:10
User entered '0'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:14
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:29
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:31:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 17:01:36

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 17:06:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 17:06:31
Data point term sent to Coder	System	12 Nov 2020 17:06:04
User entered 'ALLEGRA (FEXOFENADINE)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'SEASONAL ALLERGIES'	(b) (4) Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '180'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 17:05:15

US3202231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:44:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User closed query 'please verify as only "treatment procedures" not diagnostic procedures should be added' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:07
Query 'please verify as only "treatment procedures" not diagnostic procedures should be added' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	19 Feb 2021 20:47:51
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	19 Feb 2021 20:47:46
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 15:31:01
User opened query 'please verify as only "treatment procedures" not diagnostic procedures should be added' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:30:59
User closed query 'CT pelvis with contrast, 03Nov20, per source. Please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 21:07:41
Query 'CT pelvis with contrast, 03Nov20, per source. Please verify' answered with 'ENTERED' (Site from CRA).	Erica Osmundsen (b) (4)	12 Nov 2020 20:53:54
User opened query 'CT pelvis with contrast, 03Nov20, per source. Please verify' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:05:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:55
Query 'source also = abnormal labs of hypokalemia and elevated d-Dimer, please verify and update' canceled (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:02:53
Query 'source also = CT Pelvis with contrast, 03Nov2020, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:02:51
User opened query 'source also = abnormal labs of hypokalemia and elevated d-Dimer, please verify and update' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:48:37
User opened query 'source also = CT Pelvis with contrast, 03Nov2020, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:39:10
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	06 Nov 2020 20:33:33

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'USA-US128-2020-MRNA-1273-P301000006'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Mark'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'McKenzie'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:44
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '6035 SHALLOWFORD ROAD STE 109'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:48
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:51
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'TN'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '37421'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'US'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:16:32
User entered '3'	System	25 Nov 2020 14:44:39
User entered '2'	System	13 Nov 2020 17:31:20
User entered '1'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'USA-US128-2020-MRNA-1273-P301000006'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Mark'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'McKenzie'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:44
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '6035 SHALLOWFORD ROAD STE 109'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:48
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:51
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'TN'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '37421'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'US'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:16:32
User entered '3'	System	25 Nov 2020 14:44:39
User entered '2'	System	13 Nov 2020 17:31:20
User entered '1'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '09/Nov/2020 12:04'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'USA-US128-2020-MRNA-1273-P301000006'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Mark'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'McKenzie'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:44
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '6035 SHALLOWFORD ROAD STE 109'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:48
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:51
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'TN'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '37421'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'US'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:16:32
User entered '3'	System	25 Nov 2020 14:44:39
User entered '2'	System	13 Nov 2020 17:31:20
User entered '1'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '13/Nov/2020 17:31'	(b) (4) System	13 Nov 2020 17:31:20

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:44:25
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 17:31:20

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'USA-US128-2020-MRNA-1273-P301000006'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Mark'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'McKenzie'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:44
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '6035 SHALLOWFORD ROAD STE 109'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:48
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:51
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'TN'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '37421'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'US'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:16:32
User entered '3'	System	25 Nov 2020 14:44:39
User entered '2'	System	13 Nov 2020 17:31:20
User entered '1'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '25/Nov/2020 14:44'	(b) (4) System	25 Nov 2020 14:44:39

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:16:14
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 14:44:39

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'USA-US128-2020-MRNA-1273-P301000006'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Yes (Y)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'No (N)'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'Mark'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'McKenzie'	System	09 Nov 2020 17:04:25

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:44
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '6035 SHALLOWFORD ROAD STE 109'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:48
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:51
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'TN'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:51:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:44:25
Un-reviewed for Safety.	System	13 Nov 2020 17:31:20
DataPoint Un-verified.	System	13 Nov 2020 17:31:20
User entered empty.	System	13 Nov 2020 17:31:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered '37421'	Erica Osmundsen (b) (4)	09 Nov 2020 19:42:35

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:47
User entered 'US'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Feb 2021 21:16:32
User entered '3'	System	25 Nov 2020 14:44:39
User entered '2'	System	13 Nov 2020 17:31:20
User entered '1'	System	09 Nov 2020 17:04:44

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered '19/Feb/2021 15:16'	(b) (4) System	19 Feb 2021 21:16:32

US3202231

Folder: SAE USA-US128-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:43:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:16:32