

US3812291 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:59:55

All time stamps listed in this document are displayed in GMT

US3812291

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Participant ID

US3812291

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

US3812291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3812291

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	36
Age Units	YEARS
Age (Derived)	36
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

US3812291

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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

US3812291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	ANXIETY
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)	_____

US3812291

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	ALLERGIC RHINITIS
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)	_____

US3812291

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3812291

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3812291

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	INTERMITTENT GENERALIZED MUSCLE ACHES
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)	

US3812291

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812291

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Condition	RECURRENT ORAL APHTHOUS ULCERS
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)	_____

US3812291

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:19
Height (<i>xxx.x</i>)	62.6 in
Weight (<i>xxx.x</i>)	161.0 lb
BMI (<i>xxx.x</i>)	28.94590 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Date of assessment (dd MMM yyyy) 28 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109585

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) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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)	28 AUG 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:19
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	12:57 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:57
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 12:06

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) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	11:58 (24 HR)
Collection date and time (derived)	28 AUG 2020 11:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:01	28 AUG 2020 12:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 13:01

PC Open Date & Time

28 AUG 2020 12:26

PC Close Date & Time

28 AUG 2020 14:56

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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):

PC Time Stamp	28 AUG 2020 18:11
PC Open Date & Time	28 AUG 2020 15:51
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 21:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

30 AUG 2020 20:26

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

31 AUG 2020 20:11

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:40

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 13:02

PC Open Date & Time

28 AUG 2020 12:26

PC Close Date & Time

28 AUG 2020 14:56

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 18:12

PC Open Date & Time

28 AUG 2020 15:51

PC Close Date & Time

29 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:26

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

31 AUG 2020 20:11

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

01 SEP 2020 19:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

02 SEP 2020 19:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

03 SEP 2020 19:40

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 13:02
PC Open Date & Time	28 AUG 2020 12:26
PC Close Date & Time	28 AUG 2020 14:56

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 18:12
PC Open Date & Time	28 AUG 2020 15:51
PC Close Date & Time	29 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:01
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:26
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

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 ☒

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EAB) (1725)

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:11
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

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 ☒

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EAB) (1725)

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US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:08
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:14
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:00
Temperature (xxx.x)	96.2 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:55
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3812291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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.

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 13:21 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 13:21

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

US3812291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	13:10 (24 HR)
Collection date and time (derived)	28 SEP 2020 13:10

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:15	28 SEP 2020 13:15
Nasopharyngeal Swab 2	No		

US3812291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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 97.9 °F

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

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

PC Time Stamp 28 SEP 2020 13:52

PC Open Date & Time 28 SEP 2020 13:41

PC Close Date & Time 28 SEP 2020 16:11

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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 98.9 °F

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

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

PC Time Stamp	28 SEP 2020 19:16
PC Open Date & Time	28 SEP 2020 17:06
PC Close Date & Time	29 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

101.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 13:57

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

98.6 °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

30 SEP 2020 19:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 19:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 OCT 2020 16:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 22:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 21:23

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:52

PC Open Date & Time

28 SEP 2020 13:41

PC Close Date & Time

28 SEP 2020 16:11

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 19:16

PC Open Date & Time

28 SEP 2020 17:06

PC Close Date & Time

29 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 13:58

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 19:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 16:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 22:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

04 OCT 2020 21:23

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:53
PC Open Date & Time	28 SEP 2020 13:41
PC Close Date & Time	28 SEP 2020 16:11

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 19:16
PC Open Date & Time	28 SEP 2020 17:06
PC Close Date & Time	29 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 13:59
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

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 ☒

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US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:17
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 16:40
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 22:32
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

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 ☒

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:23
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3812291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:48 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 12:48
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

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.

US3812291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	13:00 (24 HR)
Collection date and time (derived)	26 OCT 2020 13:00

US3812291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 OCT 2020 12:53:34
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 09:00:23

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 17:06:24
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:05:16
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 13:17:59
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

06 DEC 2020 21:15:52

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

13 DEC 2020 18:39:44

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 DEC 2020 17:35:31
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

27 DEC 2020 16:46:05

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

03 JAN 2021 09:19:46

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

10 JAN 2021 10:28:40

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

17 JAN 2021 09:21:21

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 10:56:48
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

02 FEB 2021 16:46:35

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 18:12:02
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 16:54:19
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 FEB 2021 08:53:51
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 09:22:03
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 09:03:27
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 12:55:12
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 MAR 2021 08:28:35
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

28 MAR 2021 08:23:22

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

04 APR 2021 12:55:23

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

11 APR 2021 09:28:23

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

18 APR 2021 09:58:34

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

25 APR 2021 09:52:25

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

02 MAY 2021 12:01:34

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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°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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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°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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

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17 MAR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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°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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 <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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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="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"/>

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3812291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:59:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 09:22:34

US3812291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:36

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

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

Visit date (dd MMM yyyy)	22 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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US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 12:55
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

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.

US3812291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 22 MAR 2021

Collection time (00:00-23:59) 13:05 (24 HR)

Collection date and time (derived) 22 MAR 2021 13:05

US3812291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:19

Generated On: 10 Jun 2021 09:59:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812291

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:19

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812291

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812291

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812291

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

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

Visit date (dd MMM yyyy)	28 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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US3812291

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:49:37

Generated On: 10 Jun 2021 09:59:55

Date of updated informed consent (dd MMM yyyy) 28 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) 28 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 _____

US3812291

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	28 JAN 2021 13:40

US3812291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	13:45
Collection Date and Time (derived)	28 JAN 2021 13:45

US3812291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 23:55:15

Generated On: 10 Jun 2021 09:59:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

AEID	
Adverse event	FACIAL ACNE
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)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

AEID	USA-US111-2020-MRNA-1273-P30 1000023
Adverse event	MULTIPLE SCLEROSIS
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)	08 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

SUBJECT US3812291 IS A
36-YEAR-OLD FEMALE WHO
RECEIVED A NEW MEDICAL
DIAGNOSIS OF
MULTIPLE SCLEROSIS ON
DECEMBER 17, 2020. THIS
SUBJECT HAS A HISTORY OF
APHTHOUS ULCERS,
TONSILLECTOMY, AND
ANXIETY. THE SUBJECT WAS
INITIALLY SEEN BY AN
OPHTHALMOLOGIST ON DEC
14, 2020 FOR LEFT EYE PAIN
AND DECREASED PERIPHERAL
VISION THAT STARTED ON
DECEMBER 08,
2020.

THE SUBJECT UNDERWENT AN
MRI OF THE BRAIN AND
ORBITS ON DECEMBER 17, 2020.
THE FINAL
REPORT SHOWED LEFT OPTIC
NEURITIS AND SCATTERED
WHITE MATTER CEREBRAL
LESIONS. FINDINGS
WERE CONSISTENT WITH MS.
THE SUBJECT ALSO
COMPLETED AN MRI OF THE
CERVICAL SPINE AND
THORACIC SPINE ON
DECEMBER 19, 2020. FINDINGS
OF DEMYELINATING DISEASE
WERE
CONSISTENT IN BOTH
CERVICAL SPINAL CORD

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

AND THORACIC CORD.

THIS SUBJECT COMPLETED A
COURSE OF
METHYLPREDNISOLONE, 1 GM
DAILY PO FROM DECEMBER
17TH , 2020 TO DECEMBER 23RD
, 2020. THERE IS SOME
DISCREPANCY IN MR IF THIS
WAS GIVEN IV,
BUT SUBJECT VERBALIZED
ROUTE WAS INDEED PO. SHE
WAS ALSO GIVEN TEMAZEPAM
30MG Q
HS, LEXAPRO 10MG DAILY,
AND CETIRIZINE 10MG DAILY.
THIS SUBJECT HAS BEEN
GIVEN MULTIPLE
OPTIONS OF DISEASE
MODIFYING THERAPY, BUT
HAS NOT YET STARTED ONE
PER MR. WE WILL
CONTINUE TO OBTAIN SAFETY
INFORMATION FROM THIS
SUBJECT, AND ONCE STABLE
ON HER CHOSEN
THERAPY, WE WILL RESOLVE
HER SAE.

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)	

US3812291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

AEID

Adverse event

LEFT OPTIC NEURITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

US3812291

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 23:55:15

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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Name of Medication MIRENA IUD

Prophylaxis Yes ☐
No ☒

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 (1)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication SLEEP HEALTH

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 (3)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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Name of Medication SINGULAIR

Prophylaxis Yes ☒
No ☐

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	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)		01 SEP 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 (6)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT GENERALIZED
MUSCHLE ACHES

Dose per administration 800

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 (6)

Data signed: (b) (4) 30 Apr 2021 02:46:04

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	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)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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 (7)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication FACIAL ACNE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	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)		06 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 (9)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 800

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 (9)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	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)		29 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)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	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)		29 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) 29 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 (11)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication TEMAZEPAM

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 DEC 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"/>

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication WRINKLE PREVENTION

Dose per administration 20

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

If dose unit is Other, specify UNITS

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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US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2010		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 02:46:04

Generated On: 10 Jun 2021 09:59:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	20 FEB 2021	
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"/>	

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 01:45:51

Generated On: 10 Jun 2021 09:59:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 DEC 2020	BRAIN AND ORBITS MRI	Adverse Event	
19 DEC 2020	CERVICAL AND THORACIC SPINE MRI	Adverse Event	

US3812291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:59:55

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

US3812291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:59:55

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 ☐

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/DEC/2020 09:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/DEC/2020 10:03
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

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/DEC/2020 14:52
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

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/FEB/2021 11:53
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

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 14:01
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

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Apr 2021 14:44:06

Generated On: 10 Jun 2021 09:59:55

SAEID	USA-US111-2020-MRNA-1273-P301000023
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/APR/2021 08:59
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

US3812291 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812291

Form: Participant Creation

Generated On: 10 Jun 2021 09:59:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'US3812291'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Aug 2020 16:10:18

US3812291

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:18

US3812291

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:10:20

US3812291

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[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 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:18

US3812291

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'SCRN'	System	28 Aug 2020 17:47:18

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:10:21

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '36'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'YEARS'	System	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '36'	System	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Female (F)'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'I'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:30

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Aug 2020'	System	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2020'	System	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Amendment 2 (2)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:26

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:10:20

US3812291

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'I'	System	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:59:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:41:53

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:43:44
Data point term sent to Coder	System	05 Sep 2020 21:42:56
User entered 'ANXIETY'	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2015'	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2015'	System	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2015'	System	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:42:11

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 23:48:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 23:48:04
Data point term sent to Coder	System	25 Jan 2021 23:46:58
Coding entries removed.	Lyly Dang (b) (4)	25 Jan 2021 23:46:07
User entered 'allergic rhinitis' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Jan 2021 23:46:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 21:45:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 21:45:44
Data point term sent to Coder	System	05 Sep 2020 21:44:57
User entered 'ENVIRONMENTAL ALLERGIES'	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2018'	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2018'	System	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2018'	System	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:44:00

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:45:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:45:44
Data point term sent to Coder	System	05 Sep 2020 21:44:57
User entered 'TONSILLITIS'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2003'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2003'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2003'	System	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2003'	System	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2003'	System	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2003'	System	05 Sep 2020 21:44:48

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
Data point term sent to Coder	System	05 Sep 2020 21:45:58
User entered 'TONSILLECTOMY'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2003'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2003'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2003'	System	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2003'	System	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2003'	System	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2003'	System	05 Sep 2020 21:45:10

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
Data point term sent to Coder	System	05 Sep 2020 21:45:58
User entered 'BILATERAL BREAST AUGMENTATION'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2015'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2015'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2015'	System	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2015'	System	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2015'	System	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2015'	System	05 Sep 2020 21:45:35

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User closed query 'Per DM CLR: Please specify the location of INTERMITTENT MUSCLE ACHES (i.e. arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:34:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGTT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 10:19:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 10:19:44
Data point term sent to Coder	System	30 Oct 2020 14:25:10
Query 'Per DM CLR: Please specify the location of INTERMITTENT MUSCLE ACHES (i.e. arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated per source' (Site from DM).	Anya Penly (b) (4) (b) (4)	30 Oct 2020 14:24:41
Coding entries removed.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 14:24:33
User entered 'INTERMITTENT generalized MUSCLE ACHES' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	30 Oct 2020 14:24:33
User opened query 'Per DM CLR: Please specify the location of INTERMITTENT MUSCLE ACHES (i.e. arms, legs, generalized, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:56:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGTT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:35:54

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 21:35:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:46:44
Data point term sent to Coder	System	05 Sep 2020 21:45:58
User entered 'INTERMITTENT MUSCLE ACHES'	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2018'	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2018'	System	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2018'	System	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:45:51

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 21:47:44
Data point term sent to Coder	System	05 Sep 2020 21:47:00
User entered 'LATEX ALLERGY'	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'UN UNK 2005'	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2005'	System	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2005'	System	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:46:03

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Aphthous ulcer, LLT: Ulcers aphthous oral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:25:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:25:48
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
Data point term sent to Coder	System	07 Apr 2021 18:53:51
User entered 'RECURRENT ORAL APHTHOUS ULCERS'	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'UN UNK 2018'	Anyia Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered '0'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'Yes (Y)'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered empty.	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered '0'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'Jan 2018'	System	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '2018'	System	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	07 Apr 2021 18:53:25

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '11:19'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '28 Aug 2020 11:19'	System	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '62.6' in	Angie Kean (b) (4)	05 Sep 2020 21:49:53
DataPoint set to visible.	System	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '161.0' lb	Angie Kean (b) (4)	05 Sep 2020 21:49:53
DataPoint set to visible.	System	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered '28.94590'	System	05 Sep 2020 21:49:53
DataPoint set to visible.	System	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'kg/m2'	System	05 Sep 2020 21:49:53
DataPoint set to visible.	System	28 Aug 2020 17:47:30

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '98.1' F	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '58'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'bpm'	System	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '14'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'breaths/min'	System	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '102'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'mmHg'	System	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '70'	Angie Kean (b) (4)	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered 'mmHg'	System	05 Sep 2020 21:49:53

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38

US3812291

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38

US3812291

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:46:13

US3812291

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:46:13

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:58

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Urine (URINE)'	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Negative (NEGATIVE)'	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User entered empty.	System	05 Sep 2020 21:48:06

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'I'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:53:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:46:42

US3812291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:41

US3812291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:41

US3812291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	28 Aug 2020 17:47:41

US3812291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'VISIT1'	System	28 Aug 2020 17:47:41

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:54:37

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '109585'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:54:37

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:54:37

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:53:24
Query 'PER CDM: Please complete this section of the form.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:49:11
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:49:07
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:29:33

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:49:07

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:49:07

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:49:07

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:49:07

US3812291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:55

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	22 Mar 2021 18:39:35
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:48:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:27:31

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Pre-Dose (PREDOSE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '11:19'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Aug 2020 11:19'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '98.1' F	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '58'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'bpm'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '14'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'breaths/min'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '102'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '70'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered missing code ND - Not Done.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Post-Dose (POSTDOSE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12:57'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Aug 2020 12:57'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '98.4' F	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '52'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'bpm'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '16'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'breaths/min'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '110'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '76'	Angie Kean (b) (4)	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	05 Sep 2020 21:50:51

US3812291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:21:39
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:46:21

US3812291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:21:39
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:46:21

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:08:10
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' answered with 'UPDATED PER QUERY ' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	06 Oct 2020 21:06:11
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	06 Oct 2020 21:06:08
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:21:29
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:06:08
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:06:08
User entered 'Urine (URINE)'	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:06:08
User entered 'Negative (NEGATIVE)'	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:06:08
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered empty.	System	05 Sep 2020 21:48:23

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12:06'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Aug 2020 12:06'	System	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'ONCE'	System	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 17:48:08

US3812291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:48:36

US3812291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:48:36

US3812291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '11:58'	Angie Kean (b) (4)	05 Sep 2020 21:48:36

US3812291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Aug 2020 11:58'	System	05 Sep 2020 21:48:36

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Aug 2020'	Angie Kean (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12:01'	Angie Kean (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Aug 2020 12:01'	System	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered empty.	System	05 Sep 2020 21:48:48

US3812291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:58:04

US3812291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	05 Sep 2020 21:58:04

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '22b5e885-ba6b-4752-a6fe-c48a23299b3f' User entered 'Yes (Y)'	System	28 Aug 2020 18:01:48
	System	28 Aug 2020 18:01:48

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '22b5e885-ba6b-4752-a6fe-c48a23299b3f' User entered '98.4'	System	28 Aug 2020 18:01:48
	System	28 Aug 2020 18:01:48

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '22b5e885-ba6b-4752-a6fe-c48a23299b3f' User entered 'No (N)'	System	28 Aug 2020 18:01:48
	System	28 Aug 2020 18:01:48

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '22b5e885-ba6b-4752-a6fe-c48a23299b3f' User entered '28 Aug 2020 13:01'	System	28 Aug 2020 18:01:48
	System	28 Aug 2020 18:01:48

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 12:26'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 14:56'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:11:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ad24e8a0-1e6c-4811-b5c4-4eb544c43322' User entered 'Yes (Y)'	System	28 Aug 2020 23:12:01
	System	28 Aug 2020 23:12:01

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:11:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ad24e8a0-1e6c-4811-b5c4-4eb544c43322' User entered '98.8'	System	28 Aug 2020 23:12:01
	System	28 Aug 2020 23:12:01

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:11:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ad24e8a0-1e6c-4811-b5c4-4eb544c43322'	System	28 Aug 2020 23:12:01
User entered 'No (N)'	System	28 Aug 2020 23:12:01

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:11:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ad24e8a0-1e6c-4811-b5c4-4eb544c43322'	System	28 Aug 2020 23:12:01
User entered '28 Aug 2020 18:11'	System	28 Aug 2020 23:12:01

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 15:51'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 2'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:00:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fc82760f-7deb-40e6-b0d4-0357dac1195f' User entered 'Yes (Y)'	System	30 Aug 2020 02:01:15
	System	30 Aug 2020 02:01:15

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:03', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fc82760f-7deb-40e6-b0d4-0357dac1195f' User entered '97.8'	System	30 Aug 2020 02:01:15
	System	30 Aug 2020 02:01:15

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:07', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fc82760f-7deb-40e6-b0d4-0357dac1195f' User entered 'No (N)'	System	30 Aug 2020 02:01:15
	System	30 Aug 2020 02:01:15

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fc82760f-7deb-40e6-b0d4-0357dac1195f' User entered '29 Aug 2020 21:01'	System	30 Aug 2020 02:01:15
	System	30 Aug 2020 02:01:15

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 3'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:25:53', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9e20c568-39fd-4bf0-943d-4627e44ed67a' User entered 'Yes (Y)'	System	31 Aug 2020 01:26:08
	System	31 Aug 2020 01:26:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:01', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9e20c568-39fd-4bf0-943d-4627e44ed67a' User entered '97.3'	System	31 Aug 2020 01:26:08
	System	31 Aug 2020 01:26:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9e20c568-39fd-4bf0-943d-4627e44ed67a' User entered 'No (N)'	System	31 Aug 2020 01:26:08
	System	31 Aug 2020 01:26:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:06', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9e20c568-39fd-4bf0-943d-4627e44ed67a' User entered '30 Aug 2020 20:26'	System	31 Aug 2020 01:26:08
	System	31 Aug 2020 01:26:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 4'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:10:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1612d4db-805d-4286-8ab1-9c8443efe230' User entered 'Yes (Y)'	System	01 Sep 2020 01:11:08
	System	01 Sep 2020 01:11:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1612d4db-805d-4286-8ab1-9c8443efe230' User entered '97.3'	System	01 Sep 2020 01:11:08
	System	01 Sep 2020 01:11:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1612d4db-805d-4286-8ab1-9c8443efe230' User entered 'No (N)'	System	01 Sep 2020 01:11:08
	System	01 Sep 2020 01:11:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:07', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1612d4db-805d-4286-8ab1-9c8443efe230' User entered '31 Aug 2020 20:11'	System	01 Sep 2020 01:11:08
	System	01 Sep 2020 01:11:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 5'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '55989995-36bb-4699-9dec-40551d78d874'	System	02 Sep 2020 00:07:43
User entered 'Yes (Y)'	System	02 Sep 2020 00:07:43

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '55989995-36bb-4699-9dec-40551d78d874' User entered '97.5'	System	02 Sep 2020 00:07:43
	System	02 Sep 2020 00:07:43

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '55989995-36bb-4699-9dec-40551d78d874'	System	02 Sep 2020 00:07:43
User entered 'No (N)'	System	02 Sep 2020 00:07:43

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '55989995-36bb-4699-9dec-40551d78d874'	System	02 Sep 2020 00:07:43
User entered '01 Sep 2020 19:07'	System	02 Sep 2020 00:07:43

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 6'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:13:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fcd2352-7a52-4874-ae5f-e8fa7a60044a' User entered 'Yes (Y)'	System	03 Sep 2020 00:14:13
	System	03 Sep 2020 00:14:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:05', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fcd2352-7a52-4874-ae5f-e8fa7a60044a' User entered '97.4'	System	03 Sep 2020 00:14:13
	System	03 Sep 2020 00:14:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:08', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fcd2352-7a52-4874-ae5f-e8fa7a60044a' User entered 'No (N)'	System	03 Sep 2020 00:14:13
	System	03 Sep 2020 00:14:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'fcd2352-7a52-4874-ae5f-e8fa7a60044a' User entered '02 Sep 2020 19:14'	System	03 Sep 2020 00:14:13
	System	03 Sep 2020 00:14:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 7'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:01', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f4166dbb-ce98-46e2-b808-3d4375a927c7' User entered 'Yes (Y)'	System	04 Sep 2020 00:40:13
	System	04 Sep 2020 00:40:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:06', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f4166dbb-ce98-46e2-b808-3d4375a927c7' User entered '98.1'	System	04 Sep 2020 00:40:13
	System	04 Sep 2020 00:40:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:08', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f4166dbb-ce98-46e2-b808-3d4375a927c7'	System	04 Sep 2020 00:40:13
User entered 'No (N)'	System	04 Sep 2020 00:40:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f4166dbb-ce98-46e2-b808-3d4375a927c7' User entered '03 Sep 2020 19:40'	System	04 Sep 2020 00:40:13
	System	04 Sep 2020 00:40:13

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '80653414-ecbe-4447-8ae0-81c0653c3426' User entered 'None (1)'	System	28 Aug 2020 18:02:08
	System	28 Aug 2020 18:02:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '80653414-ecbe-4447-8ae0-81c0653c3426' User entered 'No (N)'	System	28 Aug 2020 18:02:08
	System	28 Aug 2020 18:02:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:01:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '80653414-ecbe-4447-8ae0-81c0653c3426' User entered 'No (N)'	System	28 Aug 2020 18:02:08
	System	28 Aug 2020 18:02:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '80653414-ecbe-4447-8ae0-81c0653c3426'	System	28 Aug 2020 18:02:08
User entered 'None (1)'	System	28 Aug 2020 18:02:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:05', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '80653414-ecbe-4447-8ae0-81c0653c3426' User entered '28 Aug 2020 13:02'	System	28 Aug 2020 18:02:08
	System	28 Aug 2020 18:02:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 12:26'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 14:56'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1358deaf-5200-4940-bac2-2403c3dfafbf' User entered 'None (1)'	System	28 Aug 2020 23:12:30
	System	28 Aug 2020 23:12:30

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:15', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1358deaf-5200-4940-bac2-2403c3dfafbf' User entered 'No (N)'	System	28 Aug 2020 23:12:30
	System	28 Aug 2020 23:12:30

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1358deaf-5200-4940-bac2-2403c3dfafbf' User entered 'No (N)'	System	28 Aug 2020 23:12:30
	System	28 Aug 2020 23:12:30

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1358deaf-5200-4940-bac2-2403c3dfafbf' User entered 'None (1)'	System	28 Aug 2020 23:12:30
	System	28 Aug 2020 23:12:30

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1358deaf-5200-4940-bac2-2403c3dfafbf' User entered '28 Aug 2020 18:12'	System	28 Aug 2020 23:12:30
	System	28 Aug 2020 23:12:30

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 15:51'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 2'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'd736cf24-b4d7-40ba-bc22-903b758cc991'	System	30 Aug 2020 02:01:37
User entered 'None (1)'	System	30 Aug 2020 02:01:37

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:18', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'd736cf24-b4d7-40ba-bc22-903b758cc991' User entered 'No (N)'	System	30 Aug 2020 02:01:37
	System	30 Aug 2020 02:01:37

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:20', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'd736cf24-b4d7-40ba-bc22-903b758cc991' User entered 'No (N)'	System	30 Aug 2020 02:01:37
	System	30 Aug 2020 02:01:37

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:24', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'd736cf24-b4d7-40ba-bc22-903b758cc991'	System	30 Aug 2020 02:01:37
User entered 'None (1)'	System	30 Aug 2020 02:01:37

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'd736cf24-b4d7-40ba-bc22-903b758cc991' User entered '29 Aug 2020 21:01'	System	30 Aug 2020 02:01:37
	System	30 Aug 2020 02:01:37

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 3'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8d380f79-5cec-4628-b272-63d2ff284008' User entered 'None (1)'	System	31 Aug 2020 01:26:33
	System	31 Aug 2020 01:26:33

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8d380f79-5cec-4628-b272-63d2ff284008' User entered 'No (N)'	System	31 Aug 2020 01:26:33
	System	31 Aug 2020 01:26:33

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:23', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8d380f79-5cec-4628-b272-63d2ff284008' User entered 'No (N)'	System	31 Aug 2020 01:26:33
	System	31 Aug 2020 01:26:33

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8d380f79-5cec-4628-b272-63d2ff284008' User entered 'None (1)'	System	31 Aug 2020 01:26:33
	System	31 Aug 2020 01:26:33

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8d380f79-5cec-4628-b272-63d2ff284008' User entered '30 Aug 2020 20:26'	System	31 Aug 2020 01:26:33
	System	31 Aug 2020 01:26:33

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 4'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '7ad7f1e3-3945-418c-8483-8dec1b29c126' User entered 'None (1)'	System	01 Sep 2020 01:11:22
	System	01 Sep 2020 01:11:22

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:12', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '7ad7f1e3-3945-418c-8483-8dec1b29c126' User entered 'No (N)'	System	01 Sep 2020 01:11:22
	System	01 Sep 2020 01:11:22

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '7ad7f1e3-3945-418c-8483-8dec1b29c126' User entered 'No (N)'	System	01 Sep 2020 01:11:22
	System	01 Sep 2020 01:11:22

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '7ad7f1e3-3945-418c-8483-8dec1b29c126'	System	01 Sep 2020 01:11:22
User entered 'None (1)'	System	01 Sep 2020 01:11:22

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:20', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '7ad7f1e3-3945-418c-8483-8dec1b29c126' User entered '31 Aug 2020 20:11'	System	01 Sep 2020 01:11:22
	System	01 Sep 2020 01:11:22

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 5'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de3507c6-d7db-4974-9fb7-e9e022a39766' User entered 'None (1)'	System	02 Sep 2020 00:07:53
	System	02 Sep 2020 00:07:53

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de3507c6-d7db-4974-9fb7-e9e022a39766' User entered 'No (N)'	System	02 Sep 2020 00:07:53
	System	02 Sep 2020 00:07:53

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de3507c6-d7db-4974-9fb7-e9e022a39766' User entered 'No (N)'	System	02 Sep 2020 00:07:53
	System	02 Sep 2020 00:07:53

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de3507c6-d7db-4974-9fb7-e9e022a39766' User entered 'None (1)'	System	02 Sep 2020 00:07:53
	System	02 Sep 2020 00:07:53

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:51', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de3507c6-d7db-4974-9fb7-e9e022a39766' User entered '01 Sep 2020 19:07'	System	02 Sep 2020 00:07:53
	System	02 Sep 2020 00:07:53

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 6'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '79c3ac77-4e74-4294-9657-212ed7a07778'	System	03 Sep 2020 00:14:34
User entered 'None (1)'	System	03 Sep 2020 00:14:34

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '79c3ac77-4e74-4294-9657-212ed7a07778' User entered 'No (N)'	System	03 Sep 2020 00:14:34
	System	03 Sep 2020 00:14:34

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '79c3ac77-4e74-4294-9657-212ed7a07778' User entered 'No (N)'	System	03 Sep 2020 00:14:34
	System	03 Sep 2020 00:14:34

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '79c3ac77-4e74-4294-9657-212ed7a07778' User entered 'None (1)'	System	03 Sep 2020 00:14:34
	System	03 Sep 2020 00:14:34

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '79c3ac77-4e74-4294-9657-212ed7a07778' User entered '02 Sep 2020 19:14'	System	03 Sep 2020 00:14:34
	System	03 Sep 2020 00:14:34

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 7'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'e4868cf4-35b3-43f0-b746-229b201a7c49'	System	04 Sep 2020 00:40:24
User entered 'None (1)'	System	04 Sep 2020 00:40:24

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:15', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'e4868cf4-35b3-43f0-b746-229b201a7c49'	System	04 Sep 2020 00:40:24
User entered 'No (N)'	System	04 Sep 2020 00:40:24

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:18', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'e4868cf4-35b3-43f0-b746-229b201a7c49' User entered 'No (N)'	System	04 Sep 2020 00:40:24
	System	04 Sep 2020 00:40:24

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'e4868cf4-35b3-43f0-b746-229b201a7c49'	System	04 Sep 2020 00:40:24
User entered 'None (1)'	System	04 Sep 2020 00:40:24

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'e4868cf4-35b3-43f0-b746-229b201a7c49'	System	04 Sep 2020 00:40:24
User entered '03 Sep 2020 19:40'	System	04 Sep 2020 00:40:24

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:11', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'None (0)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered 'No (N)'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T13:02:24', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a1ca1726-530d-4043-b455-7d011f04ab0d' User entered '28 Aug 2020 13:02'	System	28 Aug 2020 18:02:39
	System	28 Aug 2020 18:02:39

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 12:26'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 14:56'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:30', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered 'None (0)'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497'	System	28 Aug 2020 23:13:02
User entered 'No interference with activity (1)'	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered 'None (0)'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered 'None (0)'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:51', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered 'None (0)'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:53', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered 'None (0)'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:56', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497'	System	28 Aug 2020 23:13:02
User entered 'No (N)'	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-28T18:12:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '169a0aa2-c721-4b1b-9373-bbc36eaae497' User entered '28 Aug 2020 18:12'	System	28 Aug 2020 23:13:02
	System	28 Aug 2020 23:13:02

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Aug 2020 15:51'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 2'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'None (0)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:52', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered 'No (N)'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-29T21:01:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'cdb215f8-73c1-45ff-ae5e-7a9c6f115858' User entered '29 Aug 2020 21:01'	System	30 Aug 2020 02:01:58
	System	30 Aug 2020 02:01:58

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 3'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:33', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:41', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'None (0)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:46', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered 'No (N)'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-30T20:26:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27f8e04b-9dfe-4ce6-9d55-e93b7efe4475' User entered '30 Aug 2020 20:26'	System	31 Aug 2020 01:26:52
	System	31 Aug 2020 01:26:52

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 4'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:24', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:30', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'None (0)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered 'No (N)'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-08-31T20:11:34', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '89fb35f1-f28d-4d46-acac-30884208e0dd' User entered '31 Aug 2020 20:11'	System	01 Sep 2020 01:11:37
	System	01 Sep 2020 01:11:37

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 5'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:58', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:07:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:08:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'None (0)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:08:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered 'No (N)'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-01T19:08:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a618904-7ca8-4f35-bbd6-94c13b4cd49e' User entered '01 Sep 2020 19:08'	System	02 Sep 2020 00:08:06
	System	02 Sep 2020 00:08:06

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 6'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:36', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:41', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:42', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'None (0)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered 'No (N)'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-02T19:14:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '76a2c06a-bede-48af-9c87-1e0a48a40bdc' User entered '02 Sep 2020 19:14'	System	03 Sep 2020 00:14:50
	System	03 Sep 2020 00:14:50

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 7'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:26', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:30', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'None (0)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered 'No (N)'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-03T19:40:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f17003d0-b1cf-442b-b6e8-d9a6f734abba' User entered '03 Sep 2020 19:40'	System	04 Sep 2020 00:40:43
	System	04 Sep 2020 00:40:43

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:48:08

US3812291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:58:14

US3812291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '05 Sep 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 20:52:56
User entered '5 Sep 2020'	Angie Kean (b) (4)	05 Sep 2020 21:58:14

US3812291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	05 Sep 2020 21:58:14

US3812291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:58:14

US3812291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 18:39:05

US3812291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	11 Sep 2020 18:39:05

US3812291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 18:39:16

US3812291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '11 Sep 2020'	Karen Knapp (b) (4)	11 Sep 2020 18:39:16

US3812291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	11 Sep 2020 18:39:16

US3812291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Karen Knapp (b) (4)	11 Sep 2020 18:39:16

US3812291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 18:39:21

US3812291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	11 Sep 2020 18:39:21

US3812291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 15:27:27

US3812291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '18 Sep 2020'	Karen Knapp (b) (4)	18 Sep 2020 15:27:27

US3812291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Sep 2020 15:27:27

US3812291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Karen Knapp (b) (4)	18 Sep 2020 15:27:27

US3812291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 15:27:32

US3812291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	18 Sep 2020 15:27:32

US3812291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:47:50

US3812291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:47:50

US3812291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	28 Sep 2020 18:47:50

US3812291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'VISIT2'	System	28 Sep 2020 18:47:50

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:00'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Sep 2020 13:00'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:59:32
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Angie Kean (b) (4) (b) (4)	27 Oct 2020 01:42:49
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 18:58:37
User entered '96.2' F	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '68'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'bpm'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'breaths/min'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '106'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '68'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:55'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Sep 2020 13:55'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '97.9' F	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '65'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'bpm'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'breaths/min'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '112'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '70'	Breanna Galibert (b) (4)	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	28 Sep 2020 18:58:37

US3812291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:06

US3812291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:48:06

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Urine (URINE)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Negative (NEGATIVE)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered empty.	System	28 Sep 2020 18:48:14

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:21'	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Sep 2020 13:21'	System	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'ONCE'	System	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 18:49:02

US3812291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:32

US3812291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:32

US3812291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:10'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:32

US3812291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Sep 2020 13:10'	System	28 Sep 2020 18:48:32

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:15'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '28 Sep 2020 13:15'	System	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered empty.	System	28 Sep 2020 18:48:45

US3812291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	05 Oct 2020 14:36:09

US3812291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	05 Oct 2020 14:36:09

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3af7ce76-6a9b-426f-aba4-f00b16f3c213' User entered 'Yes (Y)'	System	28 Sep 2020 18:52:36
	System	28 Sep 2020 18:52:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3af7ce76-6a9b-426f-aba4-f00b16f3c213' User entered '97.9'	System	28 Sep 2020 18:52:36
	System	28 Sep 2020 18:52:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3af7ce76-6a9b-426f-aba4-f00b16f3c213' User entered 'No (N)'	System	28 Sep 2020 18:52:36
	System	28 Sep 2020 18:52:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:33', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3af7ce76-6a9b-426f-aba4-f00b16f3c213' User entered '28 Sep 2020 13:52'	System	28 Sep 2020 18:52:36
	System	28 Sep 2020 18:52:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 13:41'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 16:11'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:15:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6419ac80-35c7-4f20-b43f-3d5f454d6354' User entered 'Yes (Y)'	System	29 Sep 2020 00:16:06
	System	29 Sep 2020 00:16:06

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:15:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6419ac80-35c7-4f20-b43f-3d5f454d6354' User entered '98.9'	System	29 Sep 2020 00:16:06
	System	29 Sep 2020 00:16:06

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:15:58', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6419ac80-35c7-4f20-b43f-3d5f454d6354' User entered 'No (N)'	System	29 Sep 2020 00:16:06
	System	29 Sep 2020 00:16:06

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:01', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6419ac80-35c7-4f20-b43f-3d5f454d6354' User entered '28 Sep 2020 19:16'	System	29 Sep 2020 00:16:06
	System	29 Sep 2020 00:16:06

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 17:06'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 2'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7'	System	29 Sep 2020 18:57:50
User entered 'Yes (Y)'	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:34', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7' User entered '101.1'	System	29 Sep 2020 18:57:50
	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7'	System	29 Sep 2020 18:57:50
User entered 'Yes (Y)'	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
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 was contacted' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 07:52:13
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7' User entered '1'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 15:00:36
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	29 Sep 2020 18:57:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7' User entered '1'	System	29 Sep 2020 18:57:50
User entered '1'	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7' User entered '0'	System	29 Sep 2020 18:57:50
	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '67e54772-cf68-4d2b-8a0e-11cd586c79e7' User entered '29 Sep 2020 13:57'	System	29 Sep 2020 18:57:50
	System	29 Sep 2020 18:57:50

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 3'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:15:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1b6f2635-2981-431a-b4e7-d8e05445669e' User entered 'Yes (Y)'	System	01 Oct 2020 00:16:36
	System	01 Oct 2020 00:16:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:15:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1b6f2635-2981-431a-b4e7-d8e05445669e' User entered '98.6'	System	01 Oct 2020 00:16:36
	System	01 Oct 2020 00:16:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:15:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1b6f2635-2981-431a-b4e7-d8e05445669e' User entered 'No (N)'	System	01 Oct 2020 00:16:36
	System	01 Oct 2020 00:16:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1b6f2635-2981-431a-b4e7-d8e05445669e' User entered '30 Sep 2020 19:16'	System	01 Oct 2020 00:16:36
	System	01 Oct 2020 00:16:36

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 4'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:27:53', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f6f2eb0b-fc1a-4ed2-a7a5-88d790b93036' User entered 'Yes (Y)'	System	02 Oct 2020 00:28:15
	System	02 Oct 2020 00:28:15

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:27:58', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f6f2eb0b-fc1a-4ed2-a7a5-88d790b93036' User entered '97.7'	System	02 Oct 2020 00:28:15
	System	02 Oct 2020 00:28:15

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:07', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f6f2eb0b-fc1a-4ed2-a7a5-88d790b93036'	System	02 Oct 2020 00:28:15
User entered 'No (N)'	System	02 Oct 2020 00:28:15

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f6f2eb0b-fc1a-4ed2-a7a5-88d790b93036' User entered '01 Oct 2020 19:28'	System	02 Oct 2020 00:28:15
	System	02 Oct 2020 00:28:15

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 5'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:33', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'bedcaea7-a844-4d72-8855-ce2ff1c32d0f' User entered 'Yes (Y)'	System	02 Oct 2020 21:39:46
	System	02 Oct 2020 21:39:46

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'bedcaea7-a844-4d72-8855-ce2ff1c32d0f' User entered '97.3'	System	02 Oct 2020 21:39:46
	System	02 Oct 2020 21:39:46

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:42', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'bedcaea7-a844-4d72-8855-ce2ff1c32d0f' User entered 'No (N)'	System	02 Oct 2020 21:39:46
	System	02 Oct 2020 21:39:46

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'bedcaea7-a844-4d72-8855-ce2ff1c32d0f' User entered '02 Oct 2020 16:39'	System	02 Oct 2020 21:39:46
	System	02 Oct 2020 21:39:46

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 6'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:03', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '33102c47-46ac-4ab4-a43a-f3de92dc8883' User entered 'Yes (Y)'	System	04 Oct 2020 03:32:16
	System	04 Oct 2020 03:32:16

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:08', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '33102c47-46ac-4ab4-a43a-f3de92dc8883' User entered '98.1'	System	04 Oct 2020 03:32:16
	System	04 Oct 2020 03:32:16

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '33102c47-46ac-4ab4-a43a-f3de92dc8883' User entered 'No (N)'	System	04 Oct 2020 03:32:16
	System	04 Oct 2020 03:32:16

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '33102c47-46ac-4ab4-a43a-f3de92dc8883' User entered '03 Oct 2020 22:32'	System	04 Oct 2020 03:32:16
	System	04 Oct 2020 03:32:16

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 7'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a54147f7-3612-45e7-b2c9-6f449db6f3bc' User entered 'Yes (Y)'	System	05 Oct 2020 02:23:23
	System	05 Oct 2020 02:23:23

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a54147f7-3612-45e7-b2c9-6f449db6f3bc' User entered '97.8'	System	05 Oct 2020 02:23:23
	System	05 Oct 2020 02:23:23

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a54147f7-3612-45e7-b2c9-6f449db6f3bc' User entered 'No (N)'	System	05 Oct 2020 02:23:23
	System	05 Oct 2020 02:23:23

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a54147f7-3612-45e7-b2c9-6f449db6f3bc' User entered '04 Oct 2020 21:23'	System	05 Oct 2020 02:23:23
	System	05 Oct 2020 02:23:23

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a7f1e7f-5e34-45b2-b6df-07f3a3a1349d' User entered 'None (1)'	System	28 Sep 2020 18:52:50
	System	28 Sep 2020 18:52:50

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a7f1e7f-5e34-45b2-b6df-07f3a3a1349d' User entered 'No (N)'	System	28 Sep 2020 18:52:50
	System	28 Sep 2020 18:52:50

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a7f1e7f-5e34-45b2-b6df-07f3a3a1349d' User entered 'No (N)'	System	28 Sep 2020 18:52:50
	System	28 Sep 2020 18:52:50

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a7f1e7f-5e34-45b2-b6df-07f3a3a1349d' User entered 'None (1)'	System	28 Sep 2020 18:52:50
	System	28 Sep 2020 18:52:50

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '1a7f1e7f-5e34-45b2-b6df-07f3a3a1349d' User entered '28 Sep 2020 13:52'	System	28 Sep 2020 18:52:50
	System	28 Sep 2020 18:52:50

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 13:41'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 16:11'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27862dc0-6867-416f-96c4-0a66e2c9c049' User entered 'None (1)'	System	29 Sep 2020 00:16:34
	System	29 Sep 2020 00:16:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27862dc0-6867-416f-96c4-0a66e2c9c049' User entered 'No (N)'	System	29 Sep 2020 00:16:34
	System	29 Sep 2020 00:16:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27862dc0-6867-416f-96c4-0a66e2c9c049' User entered 'No (N)'	System	29 Sep 2020 00:16:34
	System	29 Sep 2020 00:16:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27862dc0-6867-416f-96c4-0a66e2c9c049'	System	29 Sep 2020 00:16:34
User entered 'None (1)'	System	29 Sep 2020 00:16:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27862dc0-6867-416f-96c4-0a66e2c9c049' User entered '28 Sep 2020 19:16'	System	29 Sep 2020 00:16:34
	System	29 Sep 2020 00:16:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 17:06'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 2'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de80effd-5c4d-4b14-afae-1babe11352fd'	System	29 Sep 2020 18:58:05
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 18:58:05

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de80effd-5c4d-4b14-afae-1babe11352fd' User entered 'No (N)'	System	29 Sep 2020 18:58:05
	System	29 Sep 2020 18:58:05

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:57:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de80effd-5c4d-4b14-afae-1babe11352fd' User entered 'No (N)'	System	29 Sep 2020 18:58:05
	System	29 Sep 2020 18:58:05

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:01', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de80effd-5c4d-4b14-afae-1babe11352fd' User entered 'None (1)'	System	29 Sep 2020 18:58:05
	System	29 Sep 2020 18:58:05

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'de80effd-5c4d-4b14-afae-1babe11352fd' User entered '29 Sep 2020 13:58'	System	29 Sep 2020 18:58:05
	System	29 Sep 2020 18:58:05

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 3'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8b24a589-fd6e-4946-bc9a-fe2f417e9fdf' User entered 'None (1)'	System	01 Oct 2020 00:16:49
	System	01 Oct 2020 00:16:49

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:41', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8b24a589-fd6e-4946-bc9a-fe2f417e9fdf' User entered 'No (N)'	System	01 Oct 2020 00:16:49
	System	01 Oct 2020 00:16:49

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8b24a589-fd6e-4946-bc9a-fe2f417e9fdf' User entered 'No (N)'	System	01 Oct 2020 00:16:49
	System	01 Oct 2020 00:16:49

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8b24a589-fd6e-4946-bc9a-fe2f417e9fdf' User entered 'None (1)'	System	01 Oct 2020 00:16:49
	System	01 Oct 2020 00:16:49

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:16:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8b24a589-fd6e-4946-bc9a-fe2f417e9fdf' User entered '30 Sep 2020 19:16'	System	01 Oct 2020 00:16:49
	System	01 Oct 2020 00:16:49

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 4'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '0a3031fa-19bf-4e6b-ad40-15594d8c56ee' User entered 'None (1)'	System	02 Oct 2020 00:28:29
	System	02 Oct 2020 00:28:29

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '0a3031fa-19bf-4e6b-ad40-15594d8c56ee' User entered 'No (N)'	System	02 Oct 2020 00:28:29
	System	02 Oct 2020 00:28:29

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:23', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '0a3031fa-19bf-4e6b-ad40-15594d8c56ee' User entered 'No (N)'	System	02 Oct 2020 00:28:29
	System	02 Oct 2020 00:28:29

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '0a3031fa-19bf-4e6b-ad40-15594d8c56ee' User entered 'None (1)'	System	02 Oct 2020 00:28:29
	System	02 Oct 2020 00:28:29

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '0a3031fa-19bf-4e6b-ad40-15594d8c56ee' User entered '01 Oct 2020 19:28'	System	02 Oct 2020 00:28:29
	System	02 Oct 2020 00:28:29

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 5'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'b889ed61-07c3-442c-92e0-1634c9bbd9c6' User entered 'None (1)'	System	02 Oct 2020 21:39:56
	System	02 Oct 2020 21:39:56

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'b889ed61-07c3-442c-92e0-1634c9bbd9c6' User entered 'No (N)'	System	02 Oct 2020 21:39:56
	System	02 Oct 2020 21:39:56

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:51', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'b889ed61-07c3-442c-92e0-1634c9bbd9c6' User entered 'No (N)'	System	02 Oct 2020 21:39:56
	System	02 Oct 2020 21:39:56

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:52', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'b889ed61-07c3-442c-92e0-1634c9bbd9c6' User entered 'None (1)'	System	02 Oct 2020 21:39:56
	System	02 Oct 2020 21:39:56

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:39:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'b889ed61-07c3-442c-92e0-1634c9bbd9c6' User entered '02 Oct 2020 16:39'	System	02 Oct 2020 21:39:56
	System	02 Oct 2020 21:39:56

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 6'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a3d29d-a20e-4556-9c06-e59b8b834acc' User entered 'None (1)'	System	04 Oct 2020 03:32:24
	System	04 Oct 2020 03:32:24

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a3d29d-a20e-4556-9c06-e59b8b834acc' User entered 'No (N)'	System	04 Oct 2020 03:32:24
	System	04 Oct 2020 03:32:24

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:18', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a3d29d-a20e-4556-9c06-e59b8b834acc' User entered 'No (N)'	System	04 Oct 2020 03:32:24
	System	04 Oct 2020 03:32:24

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:20', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a3d29d-a20e-4556-9c06-e59b8b834acc' User entered 'None (1)'	System	04 Oct 2020 03:32:24
	System	04 Oct 2020 03:32:24

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a3d29d-a20e-4556-9c06-e59b8b834acc' User entered '03 Oct 2020 22:32'	System	04 Oct 2020 03:32:24
	System	04 Oct 2020 03:32:24

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 7'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8bd4ab37-71de-4446-b401-fb468ddb65e3' User entered 'None (1)'	System	05 Oct 2020 02:23:34
	System	05 Oct 2020 02:23:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8bd4ab37-71de-4446-b401-fb468ddb65e3' User entered 'No (N)'	System	05 Oct 2020 02:23:34
	System	05 Oct 2020 02:23:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8bd4ab37-71de-4446-b401-fb468ddb65e3' User entered 'No (N)'	System	05 Oct 2020 02:23:34
	System	05 Oct 2020 02:23:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8bd4ab37-71de-4446-b401-fb468ddb65e3' User entered 'None (1)'	System	05 Oct 2020 02:23:34
	System	05 Oct 2020 02:23:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8bd4ab37-71de-4446-b401-fb468ddb65e3' User entered '04 Oct 2020 21:23'	System	05 Oct 2020 02:23:34
	System	05 Oct 2020 02:23:34

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:52', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:56', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:57', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:52:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'None (0)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:53:03', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered 'No (N)'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T13:53:05', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a0cc79bb-09c5-4e6f-9455-f844220cd2c5' User entered '28 Sep 2020 13:53'	System	28 Sep 2020 18:53:08
	System	28 Sep 2020 18:53:08

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 13:41'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 16:11'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:42', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'None (0)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:53', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered 'No (N)'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-28T19:16:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '45ebc607-ed44-4c45-9ba5-c316c1c18caa' User entered '28 Sep 2020 19:16'	System	29 Sep 2020 00:16:57
	System	29 Sep 2020 00:16:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '28 Sep 2020 17:06'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 2'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:23', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:30', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Some interference with activity (2)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:58:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323'	System	29 Sep 2020 18:59:10
User entered 'Prevents daily activity and requires medical attention (3)'	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:59:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323' User entered 'Yes (Y)'	System	29 Sep 2020 18:59:10
	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-29T13:59:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '4daaf5e3-4d22-4f73-b54d-73775bbce323' User entered '29 Sep 2020 13:59'	System	29 Sep 2020 18:59:10
	System	29 Sep 2020 18:59:10

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 3'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475'	System	01 Oct 2020 00:17:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475'	System	01 Oct 2020 00:17:58
User entered 'Some interference with activity (2)'	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475'	System	01 Oct 2020 00:17:58
User entered 'No interference with activity (1)'	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475' User entered 'None (0)'	System	01 Oct 2020 00:17:58
	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:46', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475'	System	01 Oct 2020 00:17:58
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:50', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475' User entered 'None (0)'	System	01 Oct 2020 00:17:58
	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:53', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475' User entered 'No (N)'	System	01 Oct 2020 00:17:58
	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-09-30T19:17:56', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '94ea16e5-56a9-4da9-8cf0-c3dfe9f8a475' User entered '30 Sep 2020 19:17'	System	01 Oct 2020 00:17:58
	System	01 Oct 2020 00:17:58

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 4'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:36', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33'	System	02 Oct 2020 00:28:57
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33'	System	02 Oct 2020 00:28:57
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:43', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered 'None (0)'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered 'None (0)'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered 'None (0)'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered 'None (0)'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:52', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered 'No (N)'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-01T19:28:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '57283165-0ba2-4166-8ee8-b8f98794ea33' User entered '01 Oct 2020 19:28'	System	02 Oct 2020 00:28:57
	System	02 Oct 2020 00:28:57

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 5'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:03', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980'	System	02 Oct 2020 21:40:35
User entered 'No interference with activity (1)'	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:06', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'None (0)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:08', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'None (0)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'None (0)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'None (0)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'None (0)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered 'No (N)'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-02T16:40:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '3a2217be-f97b-4361-a864-7ad1b884a980' User entered '02 Oct 2020 16:40'	System	02 Oct 2020 21:40:35
	System	02 Oct 2020 21:40:35

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 6'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'None (0)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered 'No (N)'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-03T22:32:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '86dcf2eb-005a-4954-85a9-8b37b69e12bb' User entered '03 Oct 2020 22:32'	System	04 Oct 2020 03:32:41
	System	04 Oct 2020 03:32:41

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Sep 2020 18:49:02
User entered 'Day 7'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:38', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:39', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:41', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:42', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'None (0)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered 'No (N)'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-04T21:23:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '38aa4c5a-f91d-463b-9554-c38d9f82a90d' User entered '04 Oct 2020 21:23'	System	05 Oct 2020 02:23:50
	System	05 Oct 2020 02:23:50

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:49:02

US3812291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:49:02

US3812291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	05 Oct 2020 14:36:19

US3812291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '05 Oct 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 20:53:14
User entered '5 Oct 2020'	Karen Knapp (b) (4)	05 Oct 2020 14:36:19

US3812291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	05 Oct 2020 14:36:19

US3812291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Karen Knapp (b) (4)	05 Oct 2020 14:36:19

US3812291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	05 Oct 2020 14:36:23

US3812291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	05 Oct 2020 14:36:23

US3812291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	12 Oct 2020 19:27:31

US3812291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12 Oct 2020'	Karen Knapp (b) (4)	12 Oct 2020 19:27:31

US3812291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	12 Oct 2020 19:27:31

US3812291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Karen Knapp (b) (4)	12 Oct 2020 19:27:31

US3812291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	12 Oct 2020 19:27:36

US3812291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	12 Oct 2020 19:27:36

US3812291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Oct 2020 20:18:59

US3812291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '19 Oct 2020'	Karen Knapp (b) (4)	19 Oct 2020 20:18:59

US3812291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	19 Oct 2020 20:18:59

US3812291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Karen Knapp (b) (4)	19 Oct 2020 20:18:59

US3812291

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Oct 2020 20:19:05

US3812291

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	19 Oct 2020 20:19:05

US3812291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:24

US3812291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:24

US3812291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:24

US3812291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'VISIT3'	System	31 Oct 2020 17:36:24

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '12:48'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '26 Oct 2020 12:48'	System	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '98.7' F	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '68'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'bpm'	System	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '16'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'breaths/min'	System	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '124'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Nov 2020 15:32:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	06 Nov 2020 15:32:26
User entered '62' reason for change: New Information	Breanna Galibert (b) (4)	06 Nov 2020 15:32:26
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	31 Oct 2020 17:36:42
User entered '32'	Breanna Galibert (b) (4)	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'mmHg'	System	31 Oct 2020 17:36:42

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49

US3812291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49

US3812291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:37:03

US3812291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:37:03

US3812291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Oct 2020 17:37:15

US3812291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	31 Oct 2020 17:37:15

US3812291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '13:00'	Breanna Galibert (b) (4)	31 Oct 2020 17:37:15

US3812291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered '26 Oct 2020 13:00'	System	31 Oct 2020 17:37:15

US3812291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Oct 2020 17:37:19

US3812291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	31 Oct 2020 17:37:19

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 64'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-30T12:53:23', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c34573d-646d-46f5-aa14-c2e69dc9c4b5' User entered 'No (N)'	System	30 Oct 2020 17:53:37
	System	30 Oct 2020 17:53:37

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-30T12:53:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c34573d-646d-46f5-aa14-c2e69dc9c4b5'	System	30 Oct 2020 17:53:37
User entered 'No (N)'	System	30 Oct 2020 17:53:37

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-10-30T12:53:34', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c34573d-646d-46f5-aa14-c2e69dc9c4b5' User entered '30 Oct 2020 12:53:34'	System	30 Oct 2020 17:53:37
	System	30 Oct 2020 17:53:37

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 71'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-07T09:00:18', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9b4568ae-5d95-438c-b408-a4bfe17ff91c' User entered 'No (N)'	System	07 Nov 2020 15:00:29
	System	07 Nov 2020 15:00:29

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-07T09:00:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9b4568ae-5d95-438c-b408-a4bfe17ff91c' User entered 'No (N)'	System	07 Nov 2020 15:00:29
	System	07 Nov 2020 15:00:29

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-07T09:00:23', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9b4568ae-5d95-438c-b408-a4bfe17ff91c' User entered '07 Nov 2020 09:00:23'	System	07 Nov 2020 15:00:29
	System	07 Nov 2020 15:00:29

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered 'Day 78'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-13T17:06:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9db2b92d-e9be-438a-9b69-928fb0c28291' User entered 'No (N)'	System	13 Nov 2020 23:06:28
	System	13 Nov 2020 23:06:28

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-13T17:06:22', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9db2b92d-e9be-438a-9b69-928fb0c28291'	System	13 Nov 2020 23:06:28
User entered 'No (N)'	System	13 Nov 2020 23:06:28

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-13T17:06:24', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9db2b92d-e9be-438a-9b69-928fb0c28291' User entered '13 Nov 2020 17:06:24'	System	13 Nov 2020 23:06:28
	System	13 Nov 2020 23:06:28

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 17:48:08

US3812291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:56:56
Data entry locked.	System	28 Aug 2020 17:48:08
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 17:48:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-23T17:05:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c5febd4d-463b-439a-9510-47c8fee41e91' User entered 'No (N)'	System	23 Nov 2020 23:05:20
	System	23 Nov 2020 23:05:20

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-23T17:05:14', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c5febd4d-463b-439a-9510-47c8fee41e91'	System	23 Nov 2020 23:05:20
User entered 'No (N)'	System	23 Nov 2020 23:05:20

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-23T17:05:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c5febd4d-463b-439a-9510-47c8fee41e91'	System	23 Nov 2020 23:05:20
User entered '23 Nov 2020 17:05:16'	System	23 Nov 2020 23:05:20

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-29T13:17:54', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8dc9ed16-3572-43c7-9a6b-777873b374c3' User entered 'No (N)'	System	29 Nov 2020 19:18:04

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-29T13:17:56', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8dc9ed16-3572-43c7-9a6b-777873b374c3'	System	29 Nov 2020 19:18:04
User entered 'No (N)'	System	29 Nov 2020 19:18:04

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-11-29T13:17:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8dc9ed16-3572-43c7-9a6b-777873b374c3'	System	29 Nov 2020 19:18:04
User entered '29 Nov 2020 13:17:59'	System	29 Nov 2020 19:18:04

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-06T21:15:47', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54db5c31-a8cc-4cf6-8b59-0d72a1f3dfef' User entered 'No (N)'	System	07 Dec 2020 03:16:01

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-06T21:15:49', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54db5c31-a8cc-4cf6-8b59-0d72a1f3dfef' User entered 'No (N)'	System	07 Dec 2020 03:16:01

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-06T21:15:52', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54db5c31-a8cc-4cf6-8b59-0d72a1f3dfef' User entered '06 Dec 2020 21:15:52'	System	07 Dec 2020 03:16:01

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-13T18:39:37', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31350cb1-9155-4d97-ae62-75d02ed51ba9'	System	14 Dec 2020 00:39:46
User entered 'No (N)'	System	14 Dec 2020 00:39:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-13T18:39:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31350cb1-9155-4d97-ae62-75d02ed51ba9'	System	14 Dec 2020 00:39:46
User entered 'No (N)'	System	14 Dec 2020 00:39:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-13T18:39:44', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31350cb1-9155-4d97-ae62-75d02ed51ba9' User entered '13 Dec 2020 18:39:44'	System	14 Dec 2020 00:39:46
	System	14 Dec 2020 00:39:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436'	System	20 Dec 2020 23:35:42
User entered 'Yes (Y)'	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:04', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436'	System	20 Dec 2020 23:35:42
User entered 'No (N)'	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:09', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436'	System	20 Dec 2020 23:35:42
User entered 'No (N)'	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436'	System	20 Dec 2020 23:35:42
User entered 'Yes (Y)'	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436'	System	20 Dec 2020 23:35:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-20T17:35:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '8c210b03-4990-4874-b6b4-b8c8ccd60436' User entered '20 Dec 2020 17:35:31'	System	20 Dec 2020 23:35:42
	System	20 Dec 2020 23:35:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-27T16:46:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54242031-23ae-4d25-9e76-9ccc4f1e758d' User entered 'No (N)'	System	27 Dec 2020 22:46:07
	System	27 Dec 2020 22:46:07

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-27T16:46:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54242031-23ae-4d25-9e76-9ccc4f1e758d' User entered 'No (N)'	System	27 Dec 2020 22:46:07
	System	27 Dec 2020 22:46:07

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2020-12-27T16:46:05', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '54242031-23ae-4d25-9e76-9ccc4f1e758d' User entered '27 Dec 2020 16:46:05'	System	27 Dec 2020 22:46:07
	System	27 Dec 2020 22:46:07

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-03T09:19:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c1b933c4-4558-4a6c-847d-009c6dfe226a' User entered 'No (N)'	System	03 Jan 2021 15:19:51
	System	03 Jan 2021 15:19:51

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-03T09:19:42', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c1b933c4-4558-4a6c-847d-009c6dfe226a' User entered 'No (N)'	System	03 Jan 2021 15:19:51

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-03T09:19:46', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'c1b933c4-4558-4a6c-847d-009c6dfe226a' User entered '03 Jan 2021 09:19:46'	System	03 Jan 2021 15:19:51
	System	03 Jan 2021 15:19:51

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-10T10:28:33', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31c9ba12-58f3-49d3-af99-e790a1ce42f7' User entered 'No (N)'	System	10 Jan 2021 16:28:42
	System	10 Jan 2021 16:28:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-10T10:28:36', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31c9ba12-58f3-49d3-af99-e790a1ce42f7' User entered 'No (N)'	System	10 Jan 2021 16:28:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-10T10:28:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '31c9ba12-58f3-49d3-af99-e790a1ce42f7' User entered '10 Jan 2021 10:28:40'	System	10 Jan 2021 16:28:42
	System	10 Jan 2021 16:28:42

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-17T09:21:17', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9aba1f4a-c057-40b3-9112-5698329ee02f' User entered 'No (N)'	System	20 Jan 2021 14:46:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-17T09:21:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9aba1f4a-c057-40b3-9112-5698329ee02f' User entered 'No (N)'	System	20 Jan 2021 14:46:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-17T09:21:21', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '9aba1f4a-c057-40b3-9112-5698329ee02f' User entered '17 Jan 2021 09:21:21'	System	20 Jan 2021 14:46:08
	System	20 Jan 2021 14:46:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:28', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782' User entered 'Yes (Y)'	System	24 Jan 2021 16:56:58
	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782'	System	24 Jan 2021 16:56:58
User entered 'No (N)'	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782' User entered 'No (N)'	System	24 Jan 2021 16:56:58
	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:40', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782' User entered 'Yes (Y)'	System	24 Jan 2021 16:56:58
	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782'	System	24 Jan 2021 16:56:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-01-24T10:56:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '99a820fe-24f7-41dd-ba0b-befe22aef782' User entered '24 Jan 2021 10:56:48'	System	24 Jan 2021 16:56:58
	System	24 Jan 2021 16:56:58

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:06', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'Yes (Y)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:10', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'Yes (Y)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:12', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:15', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'Yes (Y)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered '1'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered '1'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '1'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:25', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455' User entered '0'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:27', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:31', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'Yes (Y)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-02T16:46:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '946594ec-2f5f-4ed5-8f16-6703a9311455'	System	02 Feb 2021 22:46:46
User entered '02 Feb 2021 16:46:35'	System	02 Feb 2021 22:46:46

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-07T18:11:55', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6077c961-caca-4004-898a-e6fba80a9388' User entered 'No (N)'	System	08 Feb 2021 00:12:06
	System	08 Feb 2021 00:12:06

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-07T18:12:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6077c961-caca-4004-898a-e6fba80a9388' User entered 'No (N)'	System	08 Feb 2021 00:12:06
	System	08 Feb 2021 00:12:06

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-07T18:12:02', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6077c961-caca-4004-898a-e6fba80a9388' User entered '07 Feb 2021 18:12:02'	System	08 Feb 2021 00:12:06
	System	08 Feb 2021 00:12:06

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:53:59', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2' User entered 'Yes (Y)'	System	14 Feb 2021 22:54:27
	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:54:03', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2' User entered 'No (N)'	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:54:08', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2' User entered 'No (N)'	System	14 Feb 2021 22:54:27
	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:54:13', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2'	System	14 Feb 2021 22:54:27
User entered 'Yes (Y)'	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:54:16', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2'	System	14 Feb 2021 22:54:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-14T16:54:19', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a16406f6-17a6-4527-8697-3fd98c18d9e2' User entered '14 Feb 2021 16:54:19'	System	14 Feb 2021 22:54:27
	System	14 Feb 2021 22:54:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:29', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288' User entered 'Yes (Y)'	System	21 Feb 2021 14:54:02
	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:32', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288' User entered 'No (N)'	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:35', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288' User entered 'No (N)'	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:45', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288' User entered 'Yes (Y)'	System	21 Feb 2021 14:54:02
	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:48', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288'	System	21 Feb 2021 14:54:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-02-21T08:53:51', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '27cab62-5c5d-4ac7-964d-4fc8b6d0d288' User entered '21 Feb 2021 08:53:51'	System	21 Feb 2021 14:54:02
	System	21 Feb 2021 14:54:02

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:21:58-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ed5afc0a-aa2c-41dd-92e6-882f0504679b'	System	01 Mar 2021 15:22:08
User entered 'No (N)'	System	01 Mar 2021 15:22:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:22:01-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ed5afc0a-aa2c-41dd-92e6-882f0504679b'	System	01 Mar 2021 15:22:08
User entered 'No (N)'	System	01 Mar 2021 15:22:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:22:03-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'ed5afc0a-aa2c-41dd-92e6-882f0504679b'	System	01 Mar 2021 15:22:08
User entered '01 Mar 2021 09:22:03'	System	01 Mar 2021 15:22:08

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-07T09:03:22-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '01b4b6e2-d6da-40c4-94a8-34a5e01599e4' User entered 'No (N)'	System	07 Mar 2021 15:03:29
	System	07 Mar 2021 15:03:29

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-07T09:03:24-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '01b4b6e2-d6da-40c4-94a8-34a5e01599e4' User entered 'No (N)'	System	07 Mar 2021 15:03:29

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-07T09:03:27-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '01b4b6e2-d6da-40c4-94a8-34a5e01599e4' User entered '07 Mar 2021 09:03:27'	System	07 Mar 2021 15:03:29
	System	07 Mar 2021 15:03:29

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-14T12:55:08-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '65304d9d-dce8-4e2a-a0b7-12435cc28ec8'	System	14 Mar 2021 17:55:16
User entered 'No (N)'	System	14 Mar 2021 17:55:16

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-14T12:55:10-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '65304d9d-dce8-4e2a-a0b7-12435cc28ec8'	System	14 Mar 2021 17:55:16
User entered 'No (N)'	System	14 Mar 2021 17:55:16

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-14T12:55:12-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '65304d9d-dce8-4e2a-a0b7-12435cc28ec8' User entered '14 Mar 2021 12:55:12'	System	14 Mar 2021 17:55:16
	System	14 Mar 2021 17:55:16

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-21T08:28:09-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a68e4697-d244-4adb-bb92-024fcd0e1533'	System	21 Mar 2021 13:28:37
User entered 'Yes (Y)'	System	21 Mar 2021 13:28:37

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-21T08:28:23-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a68e4697-d244-4adb-bb92-024fcd0e1533'	System	21 Mar 2021 13:28:37
User entered 'No (N)'	System	21 Mar 2021 13:28:37

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-21T08:28:27-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a68e4697-d244-4adb-bb92-024fcd0e1533'	System	21 Mar 2021 13:28:37
User entered 'No (N)'	System	21 Mar 2021 13:28:37

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-21T08:28:31-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a68e4697-d244-4adb-bb92-024fcd0e1533'	System	21 Mar 2021 13:28:37
User entered 'No (N)'	System	21 Mar 2021 13:28:37

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-21T08:28:35-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'a68e4697-d244-4adb-bb92-024fcd0e1533'	System	21 Mar 2021 13:28:37
User entered '21 Mar 2021 08:28:35'	System	21 Mar 2021 13:28:37

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-28T08:23:16-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '11af6a6b-d27a-4586-9e9e-95d82a2efdb1'	System	28 Mar 2021 13:23:25
User entered 'No (N)'	System	28 Mar 2021 13:23:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-28T08:23:19-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '11af6a6b-d27a-4586-9e9e-95d82a2efdb1'	System	28 Mar 2021 13:23:25
User entered 'No (N)'	System	28 Mar 2021 13:23:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-28T08:23:22-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '11af6a6b-d27a-4586-9e9e-95d82a2efdb1' User entered '28 Mar 2021 08:23:22'	System	28 Mar 2021 13:23:25
	System	28 Mar 2021 13:23:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-04T12:55:18-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '12ad6920-465b-4b9c-86b9-070d394e949a' User entered 'No (N)'	System	04 Apr 2021 17:55:24

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-04T12:55:20-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '12ad6920-465b-4b9c-86b9-070d394e949a'	System	04 Apr 2021 17:55:24
User entered 'No (N)'	System	04 Apr 2021 17:55:24

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-04T12:55:23-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '12ad6920-465b-4b9c-86b9-070d394e949a'	System	04 Apr 2021 17:55:24
User entered '04 Apr 2021 12:55:23'	System	04 Apr 2021 17:55:24

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-11T09:28:15-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '46ec7946-309b-48fd-9df8-0e0a654e4606'	System	11 Apr 2021 14:28:25
User entered 'No (N)'	System	11 Apr 2021 14:28:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-11T09:28:16-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '46ec7946-309b-48fd-9df8-0e0a654e4606'	System	11 Apr 2021 14:28:25
User entered 'No (N)'	System	11 Apr 2021 14:28:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-11T09:28:23-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '46ec7946-309b-48fd-9df8-0e0a654e4606'	System	11 Apr 2021 14:28:25
User entered '11 Apr 2021 09:28:23'	System	11 Apr 2021 14:28:25

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-18T09:58:30-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6b011e42-aad1-4226-9c44-99d11d6ee6b9'	System	18 Apr 2021 14:58:36
User entered 'No (N)'	System	18 Apr 2021 14:58:36

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-18T09:58:32-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6b011e42-aad1-4226-9c44-99d11d6ee6b9'	System	18 Apr 2021 14:58:36
User entered 'No (N)'	System	18 Apr 2021 14:58:36

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-18T09:58:34-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '6b011e42-aad1-4226-9c44-99d11d6ee6b9'	System	18 Apr 2021 14:58:36
User entered '18 Apr 2021 09:58:34'	System	18 Apr 2021 14:58:36

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-25T09:52:20-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '81b16a7e-00cb-4849-baa9-a88dbe363ff8'	System	25 Apr 2021 14:52:27
User entered 'No (N)'	System	25 Apr 2021 14:52:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-25T09:52:22-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '81b16a7e-00cb-4849-baa9-a88dbe363ff8'	System	25 Apr 2021 14:52:27
User entered 'No (N)'	System	25 Apr 2021 14:52:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-04-25T09:52:25-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '81b16a7e-00cb-4849-baa9-a88dbe363ff8'	System	25 Apr 2021 14:52:27
User entered '25 Apr 2021 09:52:25'	System	25 Apr 2021 14:52:27

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-05-02T12:01:31-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f31ba14a-6253-4cde-8896-b5fbef2d9084'	System	02 May 2021 17:03:14
User entered 'No (N)'	System	02 May 2021 17:03:14

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Have you been exposed to someone with 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 (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-05-02T12:01:32-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f31ba14a-6253-4cde-8896-b5fbef2d9084'	System	02 May 2021 17:03:14
User entered 'No (N)'	System	02 May 2021 17:03:14

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-05-02T12:01:34-05:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: 'f31ba14a-6253-4cde-8896-b5fbef2d9084'	System	02 May 2021 17:03:14
User entered '02 May 2021 12:01:34'	System	02 May 2021 17:03:14

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:52:12

US3812291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:52:12
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:52:12

US3812291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:43:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:22:19-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '2fab61f2-79ee-4088-b8fd-a6e92e45bfd3'	System	01 Mar 2021 15:22:47
User entered 'Yes (Y)'	System	01 Mar 2021 15:22:47

US3812291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:55

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:43:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:22:31-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '2fab61f2-79ee-4088-b8fd-a6e92e45bfd3'	System	01 Mar 2021 15:22:47
User entered 'No (N)'	System	01 Mar 2021 15:22:47

US3812291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:43:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5877557F-D7C3-4AD3-9BCF-BF8100757788)', Time: '2021-03-01T09:22:34-06:00', User OID: 'PatientReportedOutcome (US3812291)', ODM File OID: '2fab61f2-79ee-4088-b8fd-a6e92e45bfd3' User entered '01 Mar 2021 09:22:34'	System	01 Mar 2021 15:22:47
	System	01 Mar 2021 15:22:47

US3812291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Nov 2020 15:47:20

US3812291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered '23 Nov 2020'	Karen Knapp (b) (4)	23 Nov 2020 15:47:20

US3812291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Nov 2020 15:47:20

US3812291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered empty.	Karen Knapp (b) (4)	23 Nov 2020 15:47:20

US3812291

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Nov 2020 15:47:24

US3812291

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:06:49
User entered 'I'	System	23 Nov 2020 15:47:24

US3812291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Dec 2020 16:53:39

US3812291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '24 Dec 2020'	Karen Knapp (b) (4)	24 Dec 2020 16:53:39

US3812291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	24 Dec 2020 16:53:39

US3812291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Karen Knapp (b) (4)	24 Dec 2020 16:53:39

US3812291

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Dec 2020 16:53:43

US3812291

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User entered 'I'	System	24 Dec 2020 16:53:43

US3812291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Jan 2021 19:19:21

US3812291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '23 Jan 2021'	Karen Knapp (b) (4)	23 Jan 2021 19:19:21

US3812291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Jan 2021 19:19:21

US3812291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Karen Knapp (b) (4)	23 Jan 2021 19:19:21

US3812291

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Jan 2021 19:21:18

US3812291

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User entered 'I'	System	23 Jan 2021 19:21:18

US3812291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	25 Feb 2021 21:44:35

US3812291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '25 Feb 2021'	Karen Knapp (b) (4)	25 Feb 2021 21:44:35
	(b) (4)	

US3812291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	25 Feb 2021 21:44:35

US3812291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered empty.	Karen Knapp (b) (4) (b) (4)	25 Feb 2021 21:44:35

US3812291

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	25 Feb 2021 21:44:40

US3812291

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:16:41
User entered 'I'	System	25 Feb 2021 21:44:40

US3812291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	22 Mar 2021 18:38:06
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '22 Mar 2021'	Angie Kean (b) (4)	22 Mar 2021 18:38:06
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[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 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Angie Kean (b) (4)	22 Mar 2021 18:38:06
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'VISIT4'	System	22 Mar 2021 18:38:06

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '12:55'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered '22 Mar 2021 12:55'	System	05 Apr 2021 22:18:00

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '98.1' F	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '68'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'bpm'	System	05 Apr 2021 22:18:00

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '12'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'breaths/min'	System	05 Apr 2021 22:18:00

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '100'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'mmHg'	System	05 Apr 2021 22:18:00

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '64'	Breanna Galibert (b) (4)	05 Apr 2021 22:18:00
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'mmHg'	System	05 Apr 2021 22:18:00

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02

US3812291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02

US3812291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	22 Mar 2021 18:38:18
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	22 Mar 2021 18:38:18
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	22 Mar 2021 18:38:35
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '22 Mar 2021'	Angie Kean (b) (4)	22 Mar 2021 18:38:35
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '13:05'	Angie Kean (b) (4)	22 Mar 2021 18:38:35
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered '22 Mar 2021 13:05'	System	22 Mar 2021 18:38:35

US3812291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	22 Mar 2021 18:38:39
	(b) (4)	

US3812291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:02
User entered 'I'	System	22 Mar 2021 18:38:39

US3812291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 19:24:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:42

US3812291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 19:24:19
User entered '29 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:42

US3812291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 19:24:19
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:42

US3812291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 19:24:19
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:42

US3812291

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 19:24:19
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 17:23:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 17:23:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:46
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 17:23:43
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:43

US3812291

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:23:46
User entered empty.	System	03 May 2021 17:23:43

US3812291

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:59:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:37:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Karen Knapp (b) (4)	31 Oct 2020 11:17:22

US3812291

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 20:46:02

US3812291

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 20:46:02

US3812291

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[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 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	28 Jan 2021 20:46:02

US3812291

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:46:02

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[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 21:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 15:48:58
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:53:07

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 15:48:58
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:53:07

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski (b) (4)	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Heather Cherniawski	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User entered empty.	System	28 Jan 2021 20:45:53

US3812291

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User entered empty.	System	28 Jan 2021 20:45:53

US3812291

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 20:45:35

US3812291

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 20:45:35

US3812291

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '13:40'	Heather Cherniawski (b) (4)	28 Jan 2021 20:45:35

US3812291

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User entered '28 Jan 2021 13:40'	System	28 Jan 2021 20:45:35

US3812291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Jan 2021 20:45:21

US3812291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 20:45:21

US3812291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '13:45'	Heather Cherniawski (b) (4)	28 Jan 2021 20:45:21

US3812291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:31
User entered '28 Jan 2021 13:45'	System	28 Jan 2021 20:45:21

US3812291

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:59:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:07:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:07
User entered 'Yes (Y)' reason for change: New Information	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:15:46
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:38:59

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:17:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:17:54
Data point term sent to Coder	System	30 Oct 2020 17:17:14
User entered 'facial acne'	Any Penly (b) (4)	30 Oct 2020 17:17:07
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4) (b) (4)	10 Nov 2020 20:53:50
User entered '1 Oct 2020'	Anyia Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Anyia Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[None](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Any Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:17:07

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:07
User entered 'USA-US111-2020-mRNA-1273-P301000023'	System	22 Dec 2020 14:36:30
User entered 'New'	(b) (4), (b) (6)	22 Dec 2020 14:36:30

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:08
User coded data point as SOC: Nervous system disorders, HLGT: Demyelinating disorders, HLT: Multiple sclerosis acute and progressive, PT: Multiple sclerosis, LLT: Multiple sclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:35
Data point term sent to Coder	System	21 Dec 2020 18:04:31
User entered 'Multiple Sclerosis'	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 18:04:06

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:10
User entered 'Yes (Y)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:12
User entered 'No (N)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:13
User entered 'No (N)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:14
User entered '08 Dec 2020'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:16
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 18:04:06

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:26
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:49
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:19
User entered 'Yes (Y)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:28
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:46
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:20
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:29:30
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:22
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:16:08
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 17:32:48
User entered empty.	System	21 Dec 2020 18:04:06

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:26
User entered 'Yes (Y)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:27
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:29
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:30
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:32
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:33
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:35
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:36
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:38
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:39
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:41
User entered '1'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:43
User entered 'Related (RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	22 Dec 2020 22:40:02
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 18:04:06

US3812291

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:00:16
Query 'PV Query: Please provide the final event outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae. Please keep query open until resolution is achieved.' answered with 'DUPLICATE QUERY OF OUTCOME QUERY. PLEASE REMOVE DUPLICATE QUERIES.' (Site from Safety).	Anya Penly (b) (4)	07 Apr 2021 18:56:34
User opened query 'PV Query: Please provide the final event outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 17:33:24
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:44
User closed query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 07:23:54
Query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' answered with 'updated' (Site from DM).	Lyly Dang (b) (4)	23 Dec 2020 15:41:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	23 Dec 2020 15:41:06

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 08:59:43
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:50
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:51
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:53
User entered '1'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:16:56
DataPoint Un-verified.	Angie Kean (b) (4)	20 Apr 2021 15:49:44
User entered '1' reason for change: New Information	(b) (4)	20 Apr 2021 15:49:44
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:55
User entered '0'	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:33
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:16:58
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:56
User opened query 'PV Query: Please provide the final event outcome, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:29:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 18:04:06

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:33:34
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:09
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:00:58
User entered empty.	Lyly Dang (b) (4)	21 Dec 2020 18:04:06
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:17:11
User closed query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED C AND T SPINE MRI ON 19 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 15:14:34
User closed query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED OPTIC NERVE MRI ON 17 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 15:14:21
User closed query 'PV Query: Please confirm if the subject's medical history of aphthous ulcers is a current condition or historical condition with dates. Please also add this to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:00:24
Query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED C AND T SPINE MRI ON 19 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON PROCEDURES' (Site from DM).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 19:00:15
Query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED OPTIC NERVE MRI ON 17 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON PROCEDURES' (Site from DM).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 19:00:03
Query 'PV Query: Please confirm if the subject's medical history of aphthous ulcers is a current condition or historical condition with dates. Please also add this to MH eCRF.' answered with 'MH UPDATED TO INCLUDE APHTHOUS ULCERS' (Site from Safety).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:53:48
User opened query 'PV Query: Please confirm if the subject's medical history of aphthous ulcers is a current condition or historical condition with dates. Please also add this to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 17:33:47

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional laboratory and imaging results to support the diagnosis, as well as any office visit notes from follow-up with Neurology (or other HCPs involved with the diagnosis and treatment of the study subject) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:30
User closed query 'PV Query: Please provide the results for the C and T spine MRI on 19 Dec 2020 with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:26
Query 'PV Query: Please provide the results for the C and T spine MRI on 19 Dec 2020 with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' answered with 'Sent today' (Site from Safety).	CLyly Dang (b) (4)	04 Feb 2021 21:32:29
Query 'PV Query: Please provide any additional laboratory and imaging results to support the diagnosis, as well as any office visit notes from follow-up with Neurology (or other HCPs involved with the diagnosis and treatment of the study subject) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' answered with 'Sent today' (Site from Safety).	Lyly Dang (b) (4)	04 Feb 2021 21:32:25
DataPoint Un-verified.	Lyly Dang (b) (4)	04 Feb 2021 21:12:36

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject US3812291 is a 36-year-old female who received a new medical diagnosis of multiple sclerosis on December 17, 2020. This subject has a history of aphthous ulcers, tonsillectomy, and anxiety. The subject was initially seen by an ophthalmologist on Dec 14, 2020 for left eye pain and decreased peripheral vision that started on December 08, 2020. The subject underwent an MRI of the brain and orbits on December 17, 2020. The final report showed left optic neuritis and scattered white matter cerebral lesions. Findings were consistent with MS. The subject also completed an MRI of the cervical spine and thoracic spine on December 19, 2020. Findings of demyelinating disease were consistent in both cervical spinal cord and thoracic cord. This subject completed a course of Methylprednisolone, 1 gm daily PO from December 17th , 2020 to December 23rd , 2020. There is some discrepancy in MR if this was given IV, but subject verbalized route was indeed PO. She was also given Temazepam 30mg q HS, Lexapro 10mg daily, and Cetirizine 10mg daily. This subject has been given multiple options of disease modifying therapy, but has not yet started one per MR. We will continue to obtain safety information from this subject, and once stable on her chosen therapy, we will resolve her SAE.'	Lyly Dang (b) (4) (b) (4) (b) (4)	04 Feb 2021 21:12:36
reason for change: Data Entry Error User opened query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED C AND T SPINE MRI ON 19 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:22:58
User opened query 'Per DM CLR: SAE Narrative = SUBJECT COMPLETED OPTIC NERVE MRI ON 17 DEC 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:22:46
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:01:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional laboratory and imaging results to support the diagnosis, as well as any office visit notes from follow-up with Neurology (or other HCPs involved with the diagnosis and treatment of the study subject) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:30:26
User opened query 'PV Query: Please provide the results for the C and T spine MRI on 19 Dec 2020 with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:30:08
User entered 'SUBJECT'S EDIARY NOTIFIED SITE THAT SUBJECT WAS IN CONTACT WITH A HEALTHCARE PROVIDER. . Subject reports eye pain, light sensitivity, and motion sensitivity starting 08 DEC 2020. Subject saw Ophthalmologist on 14 DEC 2020 for SXs and was referred to get an Optic Nerve MRI per subject report. Subject completed Optic Nerve MRI on 17 Dec 2020; abnormal results and DX of Multiple Sclerosis received. Subject started Methylprednisolone 1 gram PO daily starting on 17 DEC 2020 for Multiple Sclerosis. Subject completed C and T Spine MRI on 19 DEC 2020; results pending. Subject reports SXs as ongoing and denies any additional changes in health at this time. Medical records will be requested.' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	22 Dec 2020 22:40:02
User entered 'Subject's ediary notified site that subject was in contact with a healthcare provider. Subject was formally diagnosed with multiple sclerosis. Subject received methylprednisolone 1 gram daily from Dec 15th-Dec 23rd.'	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 18:04:06

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 18:04:06

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 18:04:06

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Optic nerve disorders NEC, PT: Optic neuritis, LLT: Optic neuritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:50:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:50:30
Data point term sent to Coder	System	04 Feb 2021 22:04:59
User entered 'LEFT OPTIC NEURITIS'	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Dec 2020'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4) (b) (4)	21 Dec 2020 17:52:44

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[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4)	22 Mar 2021 18:35:55
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:23
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'STILL ONGOING' (Site from DM).	Angie Kean (b) (4)	23 Feb 2021 14:28:47
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Jan 2021' reason for change: New Information	Angie Kean (b) (4)	22 Mar 2021 18:35:55
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4) (b) (4)	21 Dec 2020 17:52:44

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Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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Death

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Form: Adverse Events (3)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Angie Kean (b) (4)	20 Apr 2021 15:48:04
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Angie Kean (b) (4)	22 Mar 2021 18:35:55
	(b) (4)	
User entered '1'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: As per your previous response indicates 'updated', however there is no concomitant medication recorded that matches this AE during this timeframe. Please review or else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 07:56:40
Query 'Per CDM RQ: As per your previous response indicates 'updated', however there is no concomitant medication recorded that matches this AE during this timeframe. Please review or else clarify.' answered with 'updated. medication was actually not given for this condition' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Apr 2021 15:48:20
User entered '0' reason for change: New Information	Angie Kean (b) (4) (b) (4)	20 Apr 2021 15:48:04
User opened query 'Per CDM RQ: As per your previous response indicates 'updated', however there is no concomitant medication recorded that matches this AE during this timeframe. Please review or else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:55:14
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:55:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	06 Apr 2021 18:58:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 14:10:10
User entered '1' reason for change: New Information	Angie Kean (b) (4) (b) (4)	22 Mar 2021 18:35:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Angie Kean (b) (4)	22 Mar 2021 18:35:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4) (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 22:04:54
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4) (b) (4) (b) (4)	21 Dec 2020 17:52:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	04 Feb 2021 22:04:02
DataPoint inactivated with code reason code Data not required.	Lyly Dang (b) (4)	21 Dec 2020 17:52:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:07:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:34:59
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:21:42
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:55:41
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:16:21
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:58:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 22:00:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 22:00:39
Data point term sent to Coder	System	05 Sep 2020 22:00:10
User entered 'MIRENA IUD'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:59:24

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'CONTRACEPTION'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
Signature has been broken.	Angie Kean (b) (4) (b) (4)	17 Mar 2021 21:38:38
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered 'I'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:59:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Other (OTHER)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'UNIT'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
Signature has been broken.	Angie Kean (b) (4) (b) (4)	17 Mar 2021 21:38:42
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:59:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Other (OTHER)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'INTRAUTERINE'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'UN UNK 2019'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:59:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 21:59:24

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 21:59:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 21:59:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 22:00:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 22:00:39
Data point term sent to Coder	System	05 Sep 2020 22:00:09
User entered 'LEXAPRO'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 21:59:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'ANXIETY'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '10'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'UN UNK 2015'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 21:59:57
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 21:59:57

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 21:59:57

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 21:59:57

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 22:01:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 22:01:39
Data point term sent to Coder	System	05 Sep 2020 22:01:11
User entered 'MELATONIN'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 22:00:28

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'SLEEP HEALTH'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '5'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'UN UNK 2015'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 22:00:28
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:00:28

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:00:28

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 22:00:28

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 22:01:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 22:01:39
Data point term sent to Coder User entered 'ZYRTEC'	System Angie Kean (b) (4)	05 Sep 2020 22:01:11 05 Sep 2020 22:00:58

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'ENVIRONMENTAL ALLERGIES'	(b) (4) Angie Kean (b) (4) (b) (4)	05 Sep 2020 22:00:58

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '10'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'UN UNK 2018'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 22:00:58
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:00:58

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:00:58

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 22:00:58

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ENVIRONMENTAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:11:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ENVIRONMENTAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'Subject denies any worsening in symptoms/condition. Medication was added at subject discretion ' (Site from DM).	Angie Kean (b) (4) (b) (4)	17 Dec 2020 20:33:06
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ENVIRONMENTAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 03:36:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:26:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 14:26:53
Data point term sent to Coder	System	30 Oct 2020 14:26:15
Coding entries removed.	Any Penly (b) (4) (b) (4)	30 Oct 2020 14:26:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 22:03:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 22:03:39
Data point term sent to Coder	System	05 Sep 2020 22:03:14
User entered 'SINGULAIR'	Angie Kean (b) (4)	05 Sep 2020 22:02:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	17 Dec 2020 20:31:54
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:27:31
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated per source' (Site from DM).	Anya Penly (b) (4) (b) (4)	30 Oct 2020 14:26:22
User entered 'environmental ALLERGIES' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	30 Oct 2020 14:26:14
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 02:31:38
User entered 'ALLERGIES'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 22:02:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '10'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '01 Sep 2020'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 22:02:14
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:02:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 22:02:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 22:02:14

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:51
Data point term sent to Coder	System	30 Oct 2020 14:29:18
User entered 'ibuprofen'	Any Penly (b) (4) (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'intermittent generalized muschle aches'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '800'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mg (mg)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'as needed (PRN)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Oral (ORAL)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'un UNK 2018'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '27 Aug 2020'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User entered empty.	System	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User entered empty.	System	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:12
User entered empty.	System	30 Oct 2020 14:28:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 14:30:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 14:30:57
Data point term sent to Coder	System	30 Oct 2020 14:30:20
User entered 'influenza vaccine'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'influenza prevention'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'I'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Other (OTHER)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'dose'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'once (ONCE)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Intramuscular (INTRAMUSCULAR)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '14 Oct 2020'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '14 Oct 2020'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User entered empty.	System	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User entered empty.	System	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:14
User entered empty.	System	30 Oct 2020 14:29:31

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:56
Data point term sent to Coder	System	30 Oct 2020 17:27:28
User entered 'doxycycline'	Any Penly (b) (4) (b) (4)	30 Oct 2020 17:26:29

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'facial acne'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '100'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'mg (mg)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'once daily (QD)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Anya Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Oral (ORAL)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '06 Oct 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 20:54:16
	(b) (4)	
User entered '6 Oct 2020'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '0'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'Yes (Y)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered empty.	Anyia Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:26:29
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:26:29

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:26:29

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:26:29

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:55
Data point term sent to Coder	System	30 Oct 2020 17:27:29
User entered 'ibuprofen'	Any Penly (b) (4) (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'headache'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '800'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mg (mg)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'twice daily (BID)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Oral (ORAL)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '29 Sep 2020'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '30 Sep 2020'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Any Penly (b) (4)	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User entered '2'	System	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User entered '1'	System	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:25
User entered '804 (804)'	System	30 Oct 2020 17:27:27

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 17:28:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:28:57
Data point term sent to Coder User entered 'acetaminophen'	System Any Penly (b) (4)	30 Oct 2020 17:28:29 30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:11:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' answered with 'solicited event no AE necessary. Vax 2 previous day' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:04:20

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 03:36:49
User entered 'fever'	Any Penly (b) (4) (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '1000'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mg (mg)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'once (ONCE)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Oral (ORAL)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '29 Sep 2020'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '29 Sep 2020'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Any Penly (b) (4)	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User entered empty.	System	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User entered empty.	System	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:26
User entered empty.	System	30 Oct 2020 17:28:13

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Dec 2020 09:45:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:45:20
Data point term sent to Coder	System	24 Dec 2020 16:11:12
User entered 'METHYLPREDNISOLONE'	Breanna Galibert (b) (4) (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User closed query 'Per CDM: Please add Multiple Sclerosis to the MH eCRF as there are currently no MH that corresponds. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please add Multiple Sclerosis to the MH eCRF as there are currently no MH that corresponds. Thank you.' answered with 'ENTERED AS AN AE' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:09:40
User opened query 'Per CDM: Please add Multiple Sclerosis to the MH eCRF as there are currently no MH that corresponds. Thank you.' (Site from DM).	Breanna Galibert (b) (4)	04 Feb 2021 22:16:18
User entered 'MULTIPLE SCLEROSIS'	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 16:09:04
	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'l'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'g (g)'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '17 Dec 2020'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:46:04
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:32:49
User closed query 'Please clarify as Source notes and End Date of 23Dec2020.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 15:32:47
Query 'Please clarify as Source notes and End Date of 23Dec2020.' answered with 'updated per query' (Site from CRA).	Angie Kean (b) (4) (b) (4)	29 Apr 2021 15:12:32
Signature has been broken.	Angie Kean (b) (4) (b) (4)	29 Apr 2021 15:12:26
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	29 Apr 2021 15:12:26
User opened query 'Please clarify as Source notes and End Date of 23Dec2020.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 20:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:36:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:46:04
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:33:02
Signature has been broken.	Angie Kean (b) (4) (b) (4)	29 Apr 2021 15:12:26
User entered '23 Dec 2020' reason for change: New Information	Angie Kean (b) (4) (b) (4)	29 Apr 2021 15:12:26
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 20:36:05
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4) (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
User entered '1'	System	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
User entered '1'	System	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:29
User entered '804 (804)'	System	24 Dec 2020 16:10:42

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 00:31:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 00:31:33
Data point term sent to Coder	System	04 Feb 2021 22:09:01
User entered 'TEMAZEPAM'	Breanna Galibert (b) (4) (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'MULTIPLE SCLEROSIS'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '30'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'mg (mg)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '17 Dec 2020'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '0'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered empty.	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 22:08:21

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:01:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:01:05
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 20:57:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 20:57:54
Data point term sent to Coder User entered 'botox'	System Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:57:34 24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	24 Mar 2021 20:56:43
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'wrinkle prevention'	Angie Kean (b) (4)	24 Mar 2021 20:56:43
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered '20'	Angie Kean (b) (4)	24 Mar 2021 20:56:43
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'Other (OTHER)'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'units'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'once (ONCE)'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered empty.	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'un UNK 2010'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered '0'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	24 Mar 2021 20:56:43
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:49:37
	(b) (4)	
User entered 'un UNK 2010'	Angie Kean (b) (4)	24 Mar 2021 20:56:43
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:49:37
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User entered empty.	System	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User entered empty.	System	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:37
User entered empty.	System	24 Mar 2021 20:56:43

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:36:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:36:07
Data point term sent to Coder	System	20 Apr 2021 15:47:34
Coding entries removed.	Angie Kean (b) (4) (b) (4)	20 Apr 2021 15:46:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:44:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:44:11
Data point term sent to Coder	System	06 Apr 2021 18:58:07
User entered 'prednisone'	Angie Kean (b) (4) (b) (4)	06 Apr 2021 18:57:04

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:44:06
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	20 Apr 2021 15:46:51
	(b) (4)	
User entered 'multiple sclerosis' reason for change:	Angie Kean (b) (4)	20 Apr 2021 15:46:51
New Information	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'left optic neuritis'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'I'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'g (g)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '15 Feb 2021'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered '20 Feb 2021'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:35:22
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:45:51
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	06 Apr 2021 18:57:04
	(b) (4)	

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
User entered '1'	System	06 Apr 2021 18:57:04

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
User entered '1'	System	06 Apr 2021 18:57:04

US3812291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:36:38
User entered '804 (804)'	System	06 Apr 2021 18:57:04

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:59:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:07:03
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
Signature has been broken.	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:56:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:56:46
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:55:16
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	13 Sep 2020 11:54:23

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered '17 Dec 2020'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:57:23

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'BRAIN AND ORBITS MRI' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:58:22
User entered 'OPTIC NERVE MRI'	Anya Penly (b) (4) (b) (4)	07 Apr 2021 18:57:23

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'Adverse Event (AE)'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:57:23

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered empty.	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:57:23

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:15:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered '19 Dec 2020'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:59:10

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:15:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'CERVICAL AND THORACIC SPINE MRI'	Anyia Penly (b) (4) (b) (4)	07 Apr 2021 18:59:10

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:15:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered 'Adverse Event (AE)'	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:59:10

US3812291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:15:12
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:45:51
User entered empty.	Any Penly (b) (4) (b) (4)	07 Apr 2021 18:59:10

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 22:01:20
User entered '22/Dec/2020 09:37'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 22:01:20
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 14:37:10
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '23/Dec/2020 10:03'	(b) (4) System	23 Dec 2020 15:03:46

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:59:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Dec 2020 19:52:46
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 15:03:46

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '26/Dec/2020 14:52'	(b) (4) System	26 Dec 2020 19:52:59

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:59:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:55:59
User entered 'I'	(b) (4), (b) (6)	26 Dec 2020 19:52:59

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
User entered '05/Feb/2021 11:53'	(b) (4) System	05 Feb 2021 16:53:29

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:59:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:55:59
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 16:53:29

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered '08/Apr/2021 14:01'	System	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:59:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 18:01:27

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'USA-US111-2020-MRNA-1273-P301000023'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'No (N)'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Yes (Y)'	System	22 Dec 2020 14:36:30

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'lauren'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Larkin'	System	22 Dec 2020 14:36:30

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Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered 'clement'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'Wadsworth'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '711 Old Ballas Rd Suite 105'	System	22 Dec 2020 14:36:30

US3812291

Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'St Louis'	System	22 Dec 2020 14:36:30

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
User entered 'MO'	System	08 Apr 2021 18:01:27

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:59:17
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 18:50:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 18:01:27
Signature has been broken.	System	08 Apr 2021 18:01:27
User entered empty.	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered '63141'	System	22 Dec 2020 14:36:30

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:03:20
User entered 'US'	System	22 Dec 2020 14:37:04

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	21 Apr 2021 13:59:27
User entered '5'	System	08 Apr 2021 18:01:27
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:55:16
	(b) (4)	
User entered '4'	System	05 Feb 2021 16:53:29
User entered '3'	System	26 Dec 2020 19:52:59
User entered '2'	System	23 Dec 2020 15:03:46
User entered '1'	System	22 Dec 2020 14:37:04

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:59:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:06
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:44:06
	(b) (4)	
User entered '21/Apr/2021 08:59'	System	21 Apr 2021 13:59:27

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Folder: SAE USA-US111-2020-MRNA-1273-P301000023

Form: Safety Report Form (6)

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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)	26 Apr 2021 20:14:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:44:06
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 13:59:27