

US3742077 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:31:34

All time stamps listed in this document are displayed in GMT

US3742077

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:00:04

Generated On: 10 Jun 2021 09:31:34

Participant ID

US3742077

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

US3742077

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3742077

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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

US3742077

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3742077

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3742077

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Were any significant conditions reported?

Yes ☒

No ☐

US3742077

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Condition	ANGIOEDEMA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3742077

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3742077

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	9:40 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 9:40
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	142.5 lb
BMI (<i>xxx.x</i>)	23.76282 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742077

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3742077

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3742077

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	25 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)	

US3742077

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:08:38

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3742077

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:08:38

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

US3742077

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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

What was the participant's randomization number? 108162

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 ☒

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Height	ND - Not Done
Weight	ND - Not Done

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:40
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	064 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	099 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	064 mmHg
Diastolic Blood Pressure units	MMHG

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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)	25 AUG 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:04
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	071 mmHg
Diastolic Blood Pressure units	MMHG

US3742077

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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.

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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) _____

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 11:33

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

US3742077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

10:16 (24 HR)

Collection date and time (derived)

25 AUG 2020 10:16

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:23	25 AUG 2020 10:23
Nasopharyngeal Swab 2	No		

US3742077

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

98.5 °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

25 AUG 2020 12:05

PC Open Date & Time

25 AUG 2020 11:53

PC Close Date & Time

25 AUG 2020 14:23

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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 98.3 °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	25 AUG 2020 21:46
PC Open Date & Time	25 AUG 2020 15:18
PC Close Date & Time	26 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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 99.9 °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):

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

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

PC Time Stamp 26 AUG 2020 15:10

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

98.9 °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

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 14:22

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

99.5 °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

29 AUG 2020 19:58

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

31 AUG 2020 06:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:09

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

25 AUG 2020 12:06

PC Open Date & Time

25 AUG 2020 11:53

PC Close Date & Time

25 AUG 2020 14:23

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 21:43

PC Open Date & Time

25 AUG 2020 15:18

PC Close Date & Time

26 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

26 AUG 2020 15:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 16:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	28 AUG 2020 14:23
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 19:58

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

31 AUG 2020 06:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 12:06
PC Open Date & Time	25 AUG 2020 11:53
PC Close Date & Time	25 AUG 2020 14:23

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 21:43
PC Open Date & Time	25 AUG 2020 15:18
PC Close Date & Time	26 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

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 ☒

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:10
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

48 of 2027

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 16:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2027

EAB) (1725)

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 14:22
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2027

EAB) (1725)

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

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 ☒

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 06:41
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

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 ☒

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:56

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:56

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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)	22 SEP 2020
Time of assessment (00:00-23:59)	11:01 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:01
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	092 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	059 mmHg
Diastolic Blood Pressure units	MMHG

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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)	22 SEP 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:17
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	063 mmHg
Diastolic Blood Pressure units	MMHG

US3742077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	22 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)	

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

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) 22 SEP 2020

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

Treatment Date and Time (derived) 22 SEP 2020 11:44

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

What was the frequency of the study treatment dosing? ONCE

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

US3742077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:13 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:13

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:18	22 SEP 2020 11:18
Nasopharyngeal Swab 2	No		

US3742077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

98.6 °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

22 SEP 2020 12:17

PC Open Date & Time

22 SEP 2020 12:04

PC Close Date & Time

22 SEP 2020 14:34

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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 99.9 °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	22 SEP 2020 18:01
PC Open Date & Time	22 SEP 2020 15:29
PC Close Date & Time	23 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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 103.1 °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 23 SEP 2020 12:01

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.8 °F

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

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

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

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

PC Time Stamp 24 SEP 2020 15:38

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

25 SEP 2020 23:52

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:41

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

98.9 °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

27 SEP 2020 12:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

22 SEP 2020 12:18

PC Open Date & Time

22 SEP 2020 12:04

PC Close Date & Time

22 SEP 2020 14:34

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

22 SEP 2020 18:00

PC Open Date & Time

22 SEP 2020 15:29

PC Close Date & Time

23 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

23 SEP 2020 12:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

24 SEP 2020 15:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

25 SEP 2020 23:51

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

26 SEP 2020 12:42

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

27 SEP 2020 12:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

28 SEP 2020 12:13

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 12:18
PC Open Date & Time	22 SEP 2020 12:04
PC Close Date & Time	22 SEP 2020 14:34

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 18:01
PC Open Date & Time	22 SEP 2020 15:29
PC Close Date & Time	23 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

	Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 12:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

95 of 2027

EAB) (1725)

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 15:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

97 of 2027

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 23:51
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2027

EAB) (1725)

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:41
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

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 ☒

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

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 ☒

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:13
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3742077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:57

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3742077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	10:56 (24 HR)
Collection date and time (derived)	20 OCT 2020 10:56

US3742077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:08:38

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 11:15:48

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 07:58:35
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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	09 NOV 2020 13:21:06
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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	21 NOV 2020 21:17:13
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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	26 NOV 2020 12:54:35
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

04 DEC 2020 20:34:36

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 10:28:16
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 20:48:41

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 20:23:21
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 09:50:18

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 20:50:50

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 05:06:00
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 00:05:34

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 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	28 JAN 2021 12:25:26
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 08:43:21

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 07:13:49

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 15:36:53

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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	25 FEB 2021 09:21:02
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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	04 MAR 2021 07:06:33
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 09:21:17

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:30:29

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:52:29

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 08:27:00

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 12:29:04

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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	15 APR 2021 08:09:02
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 09:24:08

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 14:01:34
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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="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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 761

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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 <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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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"/>

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3742077

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:31:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	28 FEB 2021 14:48:09

US3742077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

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.

US3742077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

09:31 (24 HR)

Collection date and time (derived)

24 MAR 2021 09:31

US3742077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:13:55

Generated On: 10 Jun 2021 09:31:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742077

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:13:55

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742077

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742077

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:34

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3742077

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:31:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742077

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

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

Visit date (dd MMM yyyy)	8 FEB 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3742077

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:36:38

Generated On: 10 Jun 2021 09:31:34

Date of updated informed consent (dd MMM yyyy) 8 FEB 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) 8 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3742077

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 FEB 2021

Collection time (00:00-23:59)

09:07 (24 HR)

Collection date and time (derived)

8 FEB 2021 09:07

US3742077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 FEB 2021
Collection time (00:00 - 23:59)	09:12
Collection Date and Time (derived)	8 FEB 2021 09:12

US3742077

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 17:00:04

Generated On: 10 Jun 2021 09:31:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:56:24

Generated On: 10 Jun 2021 09:31:34

AEID	USA-US127-2020-MRNA-1273-P30 1000010
Adverse event	ANGIOEDEMA [LIPS]
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 2027

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:56:24

Generated On: 10 Jun 2021 09:31:34

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input 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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:56:24

Generated On: 10 Jun 2021 09:31:34

SUSAR SYNOPSIS 24
NOVEMBER 2020 – KAREN
KOTLOFF MD
VOLUNTEER US3742077
DEVELOPED FEVER 10 HOURS
AFTER HER SECOND DOSE OF
STUDY DRUG (MAX 103.1),
ACCOMPANIED BY CHILLS
(GRADE 2), HEADACHE AND
FATIGUE (GRADE 3), AND
NAUSEA (GRADE 1). THE
FOLLOWING MORNING SHE
AWOKE WITH SEVERE
ANGIOEDEMA WITHOUT
HIVES, RASH, TONGUE OR
MOUTH SWELLING,
DYSPHAGIA, DYSPNEA,
WHEEZE, OR STRIDOR. THAT
DAY SHE ALSO COMPLAINED
OF PAINFUL MUSCLES IN THE
BACK OF HER NECK MENTAL
FOGGINESS. ALL SYMPTOMS
RESOLVED WITHIN 48 HOURS.
SHE HAD SIMILAR
ANGIOEDEMA FOLLOWING A
FLU VACCINE
APPROXIMATELY ONE YEAR
AGO. SHE HAS NO KNOWN
ALLERGIES OR FAMILY
HISTORY OF ANGIOEDEMA.
SHE WAS TREATED WITH
TYLENOL FOR FEVER AND
HEADACHE, BENADRYL, AND
FAMOTIDINE. PARTICIPANT
REPORTS PREVIOUS HISTORY
OF RECEIVING RESTYLANE
INJECTIONS IN HER LIPS ON 03
MAY 2019.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Mar 2021 17:56:24

Generated On: 10 Jun 2021 09:31:34

AEID

Adverse event

SITUATIONAL DEPRESSION

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)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

327 of 2027

EAB) (1725)

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Mar 2021 17:56:24

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

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

Yes ☒

No ☐

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

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication DROSPIRENONE ETHINYL
ESTRADIOL

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 3/0.02

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT VACCINATION SITE

Dose per administration 650

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)

332 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER REACTOGENCITY

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)

334 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)		23 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)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)		23 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) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)		23 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) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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 ☐

PRODUCTION RELEASE (v12.003

340 of 2027

EAB) (1725)

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACNE
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication SITUATIONAL DEPRESSION

Dose per administration 300

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

344 of 2027

EAB) (1725)

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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)		04 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication ACNE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2027

EAB) (1725)

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO FOREHEAD

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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 2020
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 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication BOTOX INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO FOREHEAD

Dose per administration 15

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

350 of 2027

EAB) (1725)

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2019		
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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication RESTYLANE

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO LIPS

Dose per administration 1

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

If dose unit is Other, specify CC

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 X2

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	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		SUBMUCOSAL
Start date (dd MMM yyyy)		UN MAY 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2019
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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication RESTYLANE INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO BILATERAL EYES

Dose per administration .5

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

If dose unit is Other, specify CC

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 X2

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	Intraocular	<input type="radio"/>
	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	INTRADERMAL	
Start date (dd MMM yyyy)	UN DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication JUVADERM ULTRA XC
INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO LIPS

Dose per administration 1

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

If dose unit is Other, specify CC

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 1X

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	Intraocular	<input type="radio"/>
	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	INTRADERMAL	
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN JUL 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

Name of Medication JUVADERM ULTRA XC

Prophylaxis Yes ☐
No ☒

Indication COSMETIC TO NASO LABIAL
FOLDS BILATERALLY

Dose per administration 1

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

If dose unit is Other, specify CC

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 X1

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	Intraocular	<input type="radio"/>
	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	INTRADERMAL	
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN JUL 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"/>

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2027

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 21:03:48

Generated On: 10 Jun 2021 09:31:34

	Intraocular	<input type="radio"/>
	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	INTRADERMALLY	
Start date (dd MMM yyyy)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN NOV 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"/>

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	MICRONEEDLING WITH RADIOFREQUENCY	Other	ACNE SCARRING

US3742077

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:31:34

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

US3742077

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:31:34

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 ☐

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

SAEID	USA-US127-2020-MRNA-1273-P301000010
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

SAEID	USA-US127-2020-MRNA-1273-P301000010
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	30/NOV/2020 15:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 17:00:05

Generated On: 10 Jun 2021 09:31:34

SAEID	USA-US127-2020-MRNA-1273-P301000010
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/DEC/2020 17:14
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

US3742077 (Prod: University of Maryland School of Medicine)

US3742077

Form: Participant Creation

Generated On: 10 Jun 2021 09:31:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'US3742077'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:40:02

US3742077

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:22

US3742077

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:40:03

US3742077

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[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 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:22

US3742077

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'SCRN'	System	25 Aug 2020 14:46:22

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:40:04

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '29'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'YEARS'	System	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '29'	System	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:46:59

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'Aug 2020'	System	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '2020'	System	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:57:16
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Aug 2020 14:47:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 14:47:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 14:47:34
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:47:31
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:47:31

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:40:03

US3742077

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'I'	System	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:31:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	01 Oct 2020 13:57:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:49:07

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 13:58:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 13:58:55
Data point term sent to Coder	System	01 Oct 2020 13:58:07
User entered 'ANGIOEDEMA'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'Jan 2019'	System	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '2019'	System	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'Jan 2019'	System	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '2019'	System	01 Oct 2020 13:58:04

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
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)	14 Dec 2020 20:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:17:09
Data point term sent to Coder	System	14 Dec 2020 20:16:00
User entered 'acne'	Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'un UNK 2007'	Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	Kaitlin Mason (b) (4)	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'Jan 2007'	System	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '2007'	System	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered empty.	System	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered empty.	System	14 Dec 2020 20:15:45

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '9:40'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '25 Aug 2020 9:40'	System	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '65' in	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05
DataPoint set to visible.	System	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '142.5' lb	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05
DataPoint set to visible.	System	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
Amendment Manager: User entered '23.76282'	System	17 Sep 2020 00:22:23
User entered '23.8'	System	25 Aug 2020 14:51:05
DataPoint set to visible.	System	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'kg/m2'	System	25 Aug 2020 14:51:05
DataPoint set to visible.	System	25 Aug 2020 14:47:40

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:47:56
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'RECORDED IN V1' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:35:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:35:01
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:39:34
User entered '98.5' F	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 16:35:01
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:35:01
User entered '64'	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'bpm'	System	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:35:01
User entered '14'	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'breaths/min'	System	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:35:01
User entered '99'	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'mmHg'	System	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:35:01
User entered '64'	(b) (4), (b) (6)	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'mmHg'	System	25 Aug 2020 14:51:05

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17

US3742077

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17

US3742077

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:52:21

US3742077

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:52:21

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:31:34

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:48:48

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered empty.	System	25 Aug 2020 14:55:38

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:58:44

US3742077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:52:44

US3742077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:52:44

US3742077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:52:44

US3742077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'VISIT1'	System	25 Aug 2020 14:52:44

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:45:21

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '108162'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:45:21

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:45:21

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:53:40

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:53:40

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:53:40

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:53:40

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:53:40

US3742077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:34

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 16:35:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:48:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:48:41

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:48:00
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'ENTERED IN SCRIN' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:29
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:39:40
User entered '65.0' in	Sherry McCammon (b) (4) (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:34:29
User entered '142.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 16:46:20
	(b) (4)	

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:48:00
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'ENTERED IN SCRIN' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:29
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:39:40
User entered '65.0' in	Sherry McCammon (b) (4) (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:34:29
User entered '142.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 16:46:20
	(b) (4)	

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20
	(b) (4)	

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '09:40'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '25 Aug 2020 09:40'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '098.5' F	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '064'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'bpm'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '14'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'breaths/min'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '099'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '064'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:48:00
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'ENTERED IN SCRIN' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:34:29
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:39:40
User entered '65.0' in	Sherry McCammon (b) (4) (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:34:29
User entered '142.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 16:46:20
	(b) (4)	

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4) (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '12:04'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '25 Aug 2020 12:04'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '098.5' F	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '062'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'bpm'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '14'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'breaths/min'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '111'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '071'	Sherry McCammon (b) (4)	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	25 Aug 2020 16:46:20

US3742077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:48:03
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' answered with 'ENTERED IN ERROR UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:36:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 14:36:05
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:39:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:53:50

US3742077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 14:36:05
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:53:50

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:02:54
Query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'ENTERED NO' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	16 Sep 2020 16:35:20
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	16 Sep 2020 16:34:23
User opened query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:53:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	16 Sep 2020 16:34:23
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	16 Sep 2020 16:34:23
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	16 Sep 2020 16:34:23
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:24:10
Query 'per CDM: please input yes or no in this field' answered with 'NOT COLLECTED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:18:04
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:17:59
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 13:57:23
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	16 Sep 2020 16:34:23
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	25 Aug 2020 14:54:19

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '11:33'	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '25 Aug 2020 11:33'	System	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'ONCE'	System	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 15:35:57

US3742077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:00

US3742077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:00

US3742077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '10:16'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:00

US3742077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '25 Aug 2020 10:16'	System	25 Aug 2020 14:56:00

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '10:23'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '25 Aug 2020 10:23'	System	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	25 Aug 2020 14:56:12

US3742077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 16:47:00

US3742077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	25 Aug 2020 16:47:00

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:25', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9b58151c-cce9-4897-ac7d-5a69a972b179' User entered 'Yes (Y)'	System	25 Aug 2020 16:05:41
	System	25 Aug 2020 16:05:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9b58151c-cce9-4897-ac7d-5a69a972b179' User entered '98.5'	System	25 Aug 2020 16:05:41
	System	25 Aug 2020 16:05:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9b58151c-cce9-4897-ac7d-5a69a972b179'	System	25 Aug 2020 16:05:41
User entered 'No (N)'	System	25 Aug 2020 16:05:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9b58151c-cce9-4897-ac7d-5a69a972b179'	System	25 Aug 2020 16:05:41
User entered '25 Aug 2020 12:05'	System	25 Aug 2020 16:05:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 11:53'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 14:23'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:46:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '86dd8ed8-90fa-4eca-a422-399533941747' User entered 'Yes (Y)'	System	26 Aug 2020 01:46:23
	System	26 Aug 2020 01:46:23

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:46:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '86dd8ed8-90fa-4eca-a422-399533941747' User entered '98.3'	System	26 Aug 2020 01:46:23
	System	26 Aug 2020 01:46:23

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:46:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '86dd8ed8-90fa-4eca-a422-399533941747'	System	26 Aug 2020 01:46:23
User entered 'No (N)'	System	26 Aug 2020 01:46:23

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:46:19', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '86dd8ed8-90fa-4eca-a422-399533941747' User entered '25 Aug 2020 21:46'	System	26 Aug 2020 01:46:23
	System	26 Aug 2020 01:46:23

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 15:18'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 2'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a' User entered 'Yes (Y)'	System	26 Aug 2020 19:10:41
	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:19', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a' User entered '99.9'	System	26 Aug 2020 19:10:41
	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a' User entered 'Yes (Y)'	System	26 Aug 2020 19:10:41
	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
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 'TYLENOL 650 MG PO ONCE FOR PAIN AT VACCINATION SITE' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 12:03:37
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).	(b) (4), (b) (6)	08 Sep 2020 16:25:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a'	System	26 Aug 2020 19:10:41
User entered '1'	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a' User entered '0'	System	26 Aug 2020 19:10:41
	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:10:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8e7ae98c-48fa-48da-977e-ce936480192a' User entered '26 Aug 2020 15:10'	System	26 Aug 2020 19:10:41
	System	26 Aug 2020 19:10:41

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 3'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T23:59:41', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '625b81c1-71ec-4e49-b2c9-141d9673ee81' User entered 'Yes (Y)'	System	28 Aug 2020 03:59:52
	System	28 Aug 2020 03:59:52

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T23:59:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '625b81c1-71ec-4e49-b2c9-141d9673ee81' User entered '98.9'	System	28 Aug 2020 03:59:52
	System	28 Aug 2020 03:59:52

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T23:59:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '625b81c1-71ec-4e49-b2c9-141d9673ee81' User entered 'No (N)'	System	28 Aug 2020 03:59:52
	System	28 Aug 2020 03:59:52

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T23:59:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '625b81c1-71ec-4e49-b2c9-141d9673ee81' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 03:59:52
	System	28 Aug 2020 03:59:52

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 4'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a7b51744-daea-492d-80e0-83c91f30ab29' User entered 'Yes (Y)'	System	28 Aug 2020 18:22:11
	System	28 Aug 2020 18:22:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:05', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a7b51744-daea-492d-80e0-83c91f30ab29' User entered '99.0'	System	28 Aug 2020 18:22:11
	System	28 Aug 2020 18:22:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:07', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a7b51744-daea-492d-80e0-83c91f30ab29'	System	28 Aug 2020 18:22:11
User entered 'No (N)'	System	28 Aug 2020 18:22:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a7b51744-daea-492d-80e0-83c91f30ab29' User entered '28 Aug 2020 14:22'	System	28 Aug 2020 18:22:11
	System	28 Aug 2020 18:22:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 5'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4a043eea-22c8-42aa-92c8-1a0124daf58f' User entered 'Yes (Y)'	System	29 Aug 2020 23:58:56
	System	29 Aug 2020 23:58:56

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4a043eea-22c8-42aa-92c8-1a0124daf58f' User entered '99.5'	System	29 Aug 2020 23:58:56
	System	29 Aug 2020 23:58:56

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4a043eea-22c8-42aa-92c8-1a0124daf58f' User entered 'No (N)'	System	29 Aug 2020 23:58:56
	System	29 Aug 2020 23:58:56

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4a043eea-22c8-42aa-92c8-1a0124daf58f' User entered '29 Aug 2020 19:58'	System	29 Aug 2020 23:58:56
	System	29 Aug 2020 23:58:56

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 6'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cebf63f7-a6fc-4dea-bdce-924c9072337e' User entered 'Yes (Y)'	System	31 Aug 2020 10:42:19
	System	31 Aug 2020 10:42:19

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cebf63f7-a6fc-4dea-bdce-924c9072337e' User entered '99.1'	System	31 Aug 2020 10:42:19
	System	31 Aug 2020 10:42:19

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cebf63f7-a6fc-4dea-bdce-924c9072337e'	System	31 Aug 2020 10:42:19
User entered 'No (N)'	System	31 Aug 2020 10:42:19

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:18', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cebf63f7-a6fc-4dea-bdce-924c9072337e' User entered '31 Aug 2020 06:42'	System	31 Aug 2020 10:42:19
	System	31 Aug 2020 10:42:19

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 7'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T18:09:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3bf70288-3800-4794-ae9b-aeb2d4a34d2c' User entered 'Yes (Y)'	System	31 Aug 2020 22:09:11
	System	31 Aug 2020 22:09:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T18:09:05', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3bf70288-3800-4794-ae9b-aeb2d4a34d2c' User entered '99.2'	System	31 Aug 2020 22:09:11
	System	31 Aug 2020 22:09:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T18:09:07', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3bf70288-3800-4794-ae9b-aeb2d4a34d2c'	System	31 Aug 2020 22:09:11
User entered 'No (N)'	System	31 Aug 2020 22:09:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T18:09:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3bf70288-3800-4794-ae9b-aeb2d4a34d2c'	System	31 Aug 2020 22:09:11
User entered '31 Aug 2020 18:09'	System	31 Aug 2020 22:09:11

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8a981e12-2fdf-4091-949f-0af75086d207'	System	25 Aug 2020 16:06:03
User entered 'None (1)'	System	25 Aug 2020 16:06:03

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8a981e12-2fdf-4091-949f-0af75086d207' User entered 'No (N)'	System	25 Aug 2020 16:06:03
	System	25 Aug 2020 16:06:03

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8a981e12-2fdf-4091-949f-0af75086d207' User entered 'No (N)'	System	25 Aug 2020 16:06:03
	System	25 Aug 2020 16:06:03

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:05:56', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8a981e12-2fdf-4091-949f-0af75086d207'	System	25 Aug 2020 16:06:03
User entered 'None (1)'	System	25 Aug 2020 16:06:03

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8a981e12-2fdf-4091-949f-0af75086d207' User entered '25 Aug 2020 12:06'	System	25 Aug 2020 16:06:03
	System	25 Aug 2020 16:06:03

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 11:53'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 14:23'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:42:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2673a794-a52a-4308-94b7-180ecb3cdf63'	System	26 Aug 2020 01:43:16
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 01:43:16

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:42:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2673a794-a52a-4308-94b7-180ecb3cdf63' User entered 'No (N)'	System	26 Aug 2020 01:43:16
	System	26 Aug 2020 01:43:16

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2673a794-a52a-4308-94b7-180ecb3cdf63' User entered 'No (N)'	System	26 Aug 2020 01:43:16
	System	26 Aug 2020 01:43:16

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2673a794-a52a-4308-94b7-180ecb3cdf63'	System	26 Aug 2020 01:43:16
User entered 'None (1)'	System	26 Aug 2020 01:43:16

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2673a794-a52a-4308-94b7-180ecb3cdf63' User entered '25 Aug 2020 21:43'	System	26 Aug 2020 01:43:16
	System	26 Aug 2020 01:43:16

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 15:18'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 2'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:04:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1d70da96-b4fc-4511-b911-55c9a6f76387'	System	26 Aug 2020 19:08:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Aug 2020 19:08:22

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:04:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1d70da96-b4fc-4511-b911-55c9a6f76387' User entered 'No (N)'	System	26 Aug 2020 19:08:22
	System	26 Aug 2020 19:08:22

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:04:19', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1d70da96-b4fc-4511-b911-55c9a6f76387' User entered 'No (N)'	System	26 Aug 2020 19:08:22
	System	26 Aug 2020 19:08:22

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:04:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1d70da96-b4fc-4511-b911-55c9a6f76387'	System	26 Aug 2020 19:08:22
User entered 'None (1)'	System	26 Aug 2020 19:08:22

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T15:04:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1d70da96-b4fc-4511-b911-55c9a6f76387' User entered '26 Aug 2020 15:04'	System	26 Aug 2020 19:08:22
	System	26 Aug 2020 19:08:22

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 3'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '75b34e79-9832-4764-ba1b-2b80fdee60fb' User entered 'None (1)'	System	27 Aug 2020 20:01:58
	System	27 Aug 2020 20:01:58

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '75b34e79-9832-4764-ba1b-2b80fdee60fb' User entered 'No (N)'	System	27 Aug 2020 20:01:58
	System	27 Aug 2020 20:01:58

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '75b34e79-9832-4764-ba1b-2b80fdee60fb' User entered 'No (N)'	System	27 Aug 2020 20:01:58
	System	27 Aug 2020 20:01:58

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '75b34e79-9832-4764-ba1b-2b80fdee60fb' User entered 'None (1)'	System	27 Aug 2020 20:01:58
	System	27 Aug 2020 20:01:58

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:57', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '75b34e79-9832-4764-ba1b-2b80fdee60fb' User entered '27 Aug 2020 16:01'	System	27 Aug 2020 20:01:58
	System	27 Aug 2020 20:01:58

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 4'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:57', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '23d6449a-ae74-40df-a871-da6c94452bfb' User entered 'None (1)'	System	28 Aug 2020 18:23:09
	System	28 Aug 2020 18:23:09

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:59', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '23d6449a-ae74-40df-a871-da6c94452bfb' User entered 'No (N)'	System	28 Aug 2020 18:23:09
	System	28 Aug 2020 18:23:09

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:23:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '23d6449a-ae74-40df-a871-da6c94452bfb' User entered 'No (N)'	System	28 Aug 2020 18:23:09
	System	28 Aug 2020 18:23:09

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:23:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '23d6449a-ae74-40df-a871-da6c94452bfb' User entered 'None (1)'	System	28 Aug 2020 18:23:09
	System	28 Aug 2020 18:23:09

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:23:04', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '23d6449a-ae74-40df-a871-da6c94452bfb' User entered '28 Aug 2020 14:23'	System	28 Aug 2020 18:23:09
	System	28 Aug 2020 18:23:09

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 5'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9eb9a22f-f6d7-48fe-bc97-8fc3ab7e97c9'	System	29 Aug 2020 23:58:19
User entered 'None (1)'	System	29 Aug 2020 23:58:19

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9eb9a22f-f6d7-48fe-bc97-8fc3ab7e97c9'	System	29 Aug 2020 23:58:19
User entered 'No (N)'	System	29 Aug 2020 23:58:19

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9eb9a22f-f6d7-48fe-bc97-8fc3ab7e97c9' User entered 'No (N)'	System	29 Aug 2020 23:58:19
	System	29 Aug 2020 23:58:19

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9eb9a22f-f6d7-48fe-bc97-8fc3ab7e97c9'	System	29 Aug 2020 23:58:19
User entered 'None (1)'	System	29 Aug 2020 23:58:19

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T19:58:17', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9eb9a22f-f6d7-48fe-bc97-8fc3ab7e97c9' User entered '29 Aug 2020 19:58'	System	29 Aug 2020 23:58:19
	System	29 Aug 2020 23:58:19

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 6'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:56', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7417f711-bdf7-41db-8c16-b3f3601beb7b' User entered 'None (1)'	System	31 Aug 2020 10:42:08
	System	31 Aug 2020 10:42:08

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:58', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7417f711-bdf7-41db-8c16-b3f3601beb7b' User entered 'No (N)'	System	31 Aug 2020 10:42:08
	System	31 Aug 2020 10:42:08

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7417f711-bdf7-41db-8c16-b3f3601beb7b' User entered 'No (N)'	System	31 Aug 2020 10:42:08
	System	31 Aug 2020 10:42:08

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7417f711-bdf7-41db-8c16-b3f3601beb7b' User entered 'None (1)'	System	31 Aug 2020 10:42:08
	System	31 Aug 2020 10:42:08

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:42:04', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7417f711-bdf7-41db-8c16-b3f3601beb7b' User entered '31 Aug 2020 06:42'	System	31 Aug 2020 10:42:08
	System	31 Aug 2020 10:42:08

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 7'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:23', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'aa6b565a-f3aa-4573-8af4-fec54a8dc2a3'	System	31 Aug 2020 16:02:43
User entered 'None (1)'	System	31 Aug 2020 16:02:43

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'aa6b565a-f3aa-4573-8af4-fec54a8dc2a3' User entered 'No (N)'	System	31 Aug 2020 16:02:43
	System	31 Aug 2020 16:02:43

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'aa6b565a-f3aa-4573-8af4-fec54a8dc2a3'	System	31 Aug 2020 16:02:43
User entered 'No (N)'	System	31 Aug 2020 16:02:43

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'aa6b565a-f3aa-4573-8af4-fec54a8dc2a3'	System	31 Aug 2020 16:02:43
User entered 'None (1)'	System	31 Aug 2020 16:02:43

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'aa6b565a-f3aa-4573-8af4-fec54a8dc2a3' User entered '31 Aug 2020 12:01'	System	31 Aug 2020 16:02:43
	System	31 Aug 2020 16:02:43

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:08', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:17', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'None (0)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:20', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered 'No (N)'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T12:06:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '430390a5-acd4-4c3b-9160-ed8e67492e9f' User entered '25 Aug 2020 12:06'	System	25 Aug 2020 16:06:29
	System	25 Aug 2020 16:06:29

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 11:53'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 14:23'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:20', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:35', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'None (0)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered 'No (N)'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-25T21:43:42', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e8e2ec2-dfff-4136-ac53-6660916c80bb' User entered '25 Aug 2020 21:43'	System	26 Aug 2020 01:43:46
	System	26 Aug 2020 01:43:46

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Aug 2020 15:18'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 2'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:39', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:42', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered 'None (0)'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79'	System	26 Aug 2020 16:10:55
User entered 'No (N)'	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-26T12:10:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e33cc3ef-1001-4d7e-9cd5-953a53401e79' User entered '26 Aug 2020 12:10'	System	26 Aug 2020 16:10:55
	System	26 Aug 2020 16:10:55

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 3'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:35', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:39', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'None (0)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:42', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132'	System	27 Aug 2020 20:01:48
User entered 'No (N)'	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-27T16:01:44', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7ebdb489-2154-4e89-ac8c-7e82680b3132' User entered '27 Aug 2020 16:01'	System	27 Aug 2020 20:01:48
	System	27 Aug 2020 20:01:48

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 4'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:17', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:19', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:21', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'None (0)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered 'No (N)'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-28T14:22:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '292a61a8-86b8-483a-8922-3b3bf062d0fc' User entered '28 Aug 2020 14:22'	System	28 Aug 2020 18:22:39
	System	28 Aug 2020 18:22:39

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 5'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:01', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:03', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:04', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:05', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:08', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered 'None (0)'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2'	System	29 Aug 2020 16:13:17
User entered 'No (N)'	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-29T12:13:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7d7a96db-1864-4044-a8c3-a9e6f5a54bb2' User entered '29 Aug 2020 12:13'	System	29 Aug 2020 16:13:17
	System	29 Aug 2020 16:13:17

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 6'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:44', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:46', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'None (0)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered 'No (N)'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T06:41:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c74eb848-e376-45c6-8fa5-a73b51eb540a' User entered '31 Aug 2020 06:41'	System	31 Aug 2020 10:41:53
	System	31 Aug 2020 10:41:53

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 7'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'None (0)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered 'No (N)'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-08-31T12:01:20', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c1e3fedb-21ed-4cc7-95f4-21687a789feb' User entered '31 Aug 2020 12:01'	System	31 Aug 2020 16:02:32
	System	31 Aug 2020 16:02:32

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:35:57

US3742077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:47:26

US3742077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:47:26

US3742077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:47:26

US3742077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:47:26

US3742077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 14:54:02

US3742077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	02 Sep 2020 14:54:02

US3742077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:26:41

US3742077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:26:41

US3742077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:26:41

US3742077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:26:41

US3742077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:26:51

US3742077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	08 Sep 2020 16:26:51

US3742077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:53:02

US3742077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:53:02

US3742077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:53:02

US3742077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:53:02

US3742077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:52:50

US3742077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	16 Sep 2020 13:52:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:22:33

US3742077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:22:33

US3742077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:22:33

US3742077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'VISIT2'	System	22 Sep 2020 18:22:33

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '11:01'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '22 Sep 2020 11:01'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '097.5' F	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '068'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'bpm'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'breaths/min'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '092'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'Per CDM Re-query: Please confirm if out of range value is CS/NCS. Report AE if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:27:53
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).	(b) (4), (b) (6)	25 Sep 2020 14:27:52
Query 'Per CDM Re-query: Please confirm if out of range value is CS/NCS. Report AE if appropriate. ' answered with 'NCS' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 13:58:55
User opened query 'Per CDM Re-query: Please confirm if out of range value is CS/NCS. Report AE if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:52:07
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 with 'BLOOD PRESSURE OBTAINED ' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 18:25:20
User opened query 'Diastolic Blood Pressure reported System 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).		22 Sep 2020 18:24:50
User entered '059'	(b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '12:17'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '22 Sep 2020 12:17'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '076'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'bpm'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'breaths/min'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '107'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '063'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'mmHg'	System	22 Sep 2020 18:24:50

US3742077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:26:17

US3742077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:26:17

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User closed query 'per CDM: if FSH sample was not collected, collection date/time fields should be blank -- please use drop down menu to remove data, or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:04:11
Query 'per CDM: if FSH sample was not collected, collection date/time fields should be blank -- please use drop down menu to remove data, or clarify' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 20:09:35
User opened query 'per CDM: if FSH sample was not collected, collection date/time fields should be blank -- please use drop down menu to remove data, or clarify' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:41:34
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 20:09:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 20:09:31
User entered '11:11'	(b) (4), (b) (6)	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:31:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	21 Oct 2020 20:09:31
User entered '22 Sep 2020 11:11'	System	22 Sep 2020 18:27:19

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '11:44'	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '22 Sep 2020 11:44'	System	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'ONCE'	System	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 15:49:23

US3742077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:54

US3742077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:54

US3742077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '11:13'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:54

US3742077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '22 Sep 2020 11:13'	System	22 Sep 2020 18:27:54

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '11:18'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '22 Sep 2020 11:18'	System	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	22 Sep 2020 18:27:39

US3742077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:28:27

US3742077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	22 Sep 2020 18:28:27

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:42', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c548eac0-a9f8-435c-a24f-541525b5db49'	System	22 Sep 2020 16:17:53
User entered 'Yes (Y)'	System	22 Sep 2020 16:17:53

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c548eac0-a9f8-435c-a24f-541525b5db49' User entered '98.6'	System	22 Sep 2020 16:17:53
	System	22 Sep 2020 16:17:53

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c548eac0-a9f8-435c-a24f-541525b5db49'	System	22 Sep 2020 16:17:53
User entered 'No (N)'	System	22 Sep 2020 16:17:53

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:51', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c548eac0-a9f8-435c-a24f-541525b5db49' User entered '22 Sep 2020 12:17'	System	22 Sep 2020 16:17:53
	System	22 Sep 2020 16:17:53

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 12:04'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 14:34'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2575fa05-cc6f-4a72-bd03-28c2e95a379d' User entered 'Yes (Y)'	System	22 Sep 2020 22:01:58
	System	22 Sep 2020 22:01:58

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2575fa05-cc6f-4a72-bd03-28c2e95a379d' User entered '99.9'	System	22 Sep 2020 22:01:58
	System	22 Sep 2020 22:01:58

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2575fa05-cc6f-4a72-bd03-28c2e95a379d'	System	22 Sep 2020 22:01:58
User entered 'No (N)'	System	22 Sep 2020 22:01:58

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:52', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '2575fa05-cc6f-4a72-bd03-28c2e95a379d' User entered '22 Sep 2020 18:01'	System	22 Sep 2020 22:01:58
	System	22 Sep 2020 22:01:58

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 15:29'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 2'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:00:54', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab' User entered 'Yes (Y)'	System	23 Sep 2020 16:04:42
	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:00:59', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab' User entered '103.1'	System	23 Sep 2020 16:04:42
	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:01', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab'	System	23 Sep 2020 16:04:42
User entered 'Yes (Y)'	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
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 'TYLENOL 1000 MG PO PRN FEVER ' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 17:53:47
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).	(b) (4), (b) (6)	29 Sep 2020 21:56:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab'	System	23 Sep 2020 16:04:42
User entered '1'	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab' User entered '0'	System	23 Sep 2020 16:04:42
	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '39dad1f2-6c38-4974-9974-32f51c05a8ab' User entered '23 Sep 2020 12:01'	System	23 Sep 2020 16:04:42
	System	23 Sep 2020 16:04:42

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 3'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:17', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73'	System	24 Sep 2020 19:38:40
User entered 'Yes (Y)'	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:20', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73' User entered '99.8'	System	24 Sep 2020 19:38:40
	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73'	System	24 Sep 2020 19:38:40
User entered 'Yes (Y)'	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
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 'TYLENOL 1000 MG PO PRN FEVER ' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 17:55:49
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).	(b) (4), (b) (6)	29 Sep 2020 21:57:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73'	System	24 Sep 2020 19:38:40
User entered '1'	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73' User entered '0'	System	24 Sep 2020 19:38:40
	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:35', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6b8da375-d8a3-40bb-ad56-322e06cf1a73'	System	24 Sep 2020 19:38:40
User entered '24 Sep 2020 15:38'	System	24 Sep 2020 19:38:40

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 4'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '54ea7261-e024-4d29-af04-97688c632b90' User entered 'Yes (Y)'	System	26 Sep 2020 03:52:09
	System	26 Sep 2020 03:52:09

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:52:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '54ea7261-e024-4d29-af04-97688c632b90' User entered '98.8'	System	26 Sep 2020 03:52:09
	System	26 Sep 2020 03:52:09

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:52:04', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '54ea7261-e024-4d29-af04-97688c632b90'	System	26 Sep 2020 03:52:09
User entered 'No (N)'	System	26 Sep 2020 03:52:09

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:52:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '54ea7261-e024-4d29-af04-97688c632b90' User entered '25 Sep 2020 23:52'	System	26 Sep 2020 03:52:09
	System	26 Sep 2020 03:52:09

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 5'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'fcbfd3ad-ccce-4f79-a6d5-2793342b767e' User entered 'Yes (Y)'	System	26 Sep 2020 16:41:38
	System	26 Sep 2020 16:41:38

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'fcbfd3ad-ccce-4f79-a6d5-2793342b767e' User entered '99.0'	System	26 Sep 2020 16:41:38
	System	26 Sep 2020 16:41:38

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'fcbfd3ad-ccce-4f79-a6d5-2793342b767e' User entered 'No (N)'	System	26 Sep 2020 16:41:38
	System	26 Sep 2020 16:41:38

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'fcbfd3ad-ccce-4f79-a6d5-2793342b767e' User entered '26 Sep 2020 12:41'	System	26 Sep 2020 16:41:38
	System	26 Sep 2020 16:41:38

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 6'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e7c919e-316b-4657-849f-4759da7f78a1' User entered 'Yes (Y)'	System	27 Sep 2020 16:27:20
	System	27 Sep 2020 16:27:20

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e7c919e-316b-4657-849f-4759da7f78a1' User entered '98.9'	System	27 Sep 2020 16:27:20
	System	27 Sep 2020 16:27:20

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:17', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e7c919e-316b-4657-849f-4759da7f78a1' User entered 'No (N)'	System	27 Sep 2020 16:27:20
	System	27 Sep 2020 16:27:20

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:18', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4e7c919e-316b-4657-849f-4759da7f78a1' User entered '27 Sep 2020 12:27'	System	27 Sep 2020 16:27:20
	System	27 Sep 2020 16:27:20

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 7'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:14:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '297d1ad0-37ec-4405-86e1-dc9f892c544c' User entered 'Yes (Y)'	System	28 Sep 2020 16:14:16
	System	28 Sep 2020 16:14:16

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:14:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '297d1ad0-37ec-4405-86e1-dc9f892c544c' User entered '99.0'	System	28 Sep 2020 16:14:16
	System	28 Sep 2020 16:14:16

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:14:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '297d1ad0-37ec-4405-86e1-dc9f892c544c' User entered 'No (N)'	System	28 Sep 2020 16:14:16
	System	28 Sep 2020 16:14:16

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:14:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '297d1ad0-37ec-4405-86e1-dc9f892c544c' User entered '28 Sep 2020 12:14'	System	28 Sep 2020 16:14:16
	System	28 Sep 2020 16:14:16

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bc86f7de-efb4-4b33-b2ab-81761151bb30' User entered 'None (1)'	System	22 Sep 2020 16:18:42
	System	22 Sep 2020 16:18:42

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:23', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bc86f7de-efb4-4b33-b2ab-81761151bb30' User entered 'No (N)'	System	22 Sep 2020 16:18:42
	System	22 Sep 2020 16:18:42

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bc86f7de-efb4-4b33-b2ab-81761151bb30' User entered 'No (N)'	System	22 Sep 2020 16:18:42
	System	22 Sep 2020 16:18:42

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bc86f7de-efb4-4b33-b2ab-81761151bb30' User entered 'None (1)'	System	22 Sep 2020 16:18:42
	System	22 Sep 2020 16:18:42

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:39', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bc86f7de-efb4-4b33-b2ab-81761151bb30' User entered '22 Sep 2020 12:18'	System	22 Sep 2020 16:18:42
	System	22 Sep 2020 16:18:42

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 12:04'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 14:34'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T17:58:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '88db5b9b-6b07-4ec9-82f6-8dff7eb6109'	System	22 Sep 2020 22:00:38
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 22:00:38

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T17:59:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '88db5b9b-6b07-4ec9-82f6-8dff7eb6109'	System	22 Sep 2020 22:00:38
User entered 'No (N)'	System	22 Sep 2020 22:00:38

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '88db5b9b-6b07-4ec9-82f6-8dff7eb6109'	System	22 Sep 2020 22:00:38
User entered 'No (N)'	System	22 Sep 2020 22:00:38

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '88db5b9b-6b07-4ec9-82f6-8dff7eb6109'	System	22 Sep 2020 22:00:38
User entered 'None (1)'	System	22 Sep 2020 22:00:38

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '88db5b9b-6b07-4ec9-82f6-8dff7eb6109' User entered '22 Sep 2020 18:00'	System	22 Sep 2020 22:00:38
	System	22 Sep 2020 22:00:38

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 15:29'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 2'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:41', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c943daed-e265-40a6-a639-74079a6fc83f'	System	24 Sep 2020 19:38:10
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 19:38:10

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c943daed-e265-40a6-a639-74079a6fc83f' User entered 'No (N)'	System	24 Sep 2020 19:38:10
	System	24 Sep 2020 19:38:10

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c943daed-e265-40a6-a639-74079a6fc83f' User entered 'No (N)'	System	24 Sep 2020 19:38:10
	System	24 Sep 2020 19:38:10

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c943daed-e265-40a6-a639-74079a6fc83f' User entered 'None (1)'	System	24 Sep 2020 19:38:10
	System	24 Sep 2020 19:38:10

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:57', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c943daed-e265-40a6-a639-74079a6fc83f' User entered '23 Sep 2020 12:02'	System	24 Sep 2020 19:38:10
	System	24 Sep 2020 19:38:10

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 3'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:07', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '863bf179-07dc-4379-9f63-9fd2c0af579b'	System	24 Sep 2020 19:39:16
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 19:39:16

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:08', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '863bf179-07dc-4379-9f63-9fd2c0af579b'	System	24 Sep 2020 19:39:16
User entered 'No (N)'	System	24 Sep 2020 19:39:16

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '863bf179-07dc-4379-9f63-9fd2c0af579b' User entered 'No (N)'	System	24 Sep 2020 19:39:16
	System	24 Sep 2020 19:39:16

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '863bf179-07dc-4379-9f63-9fd2c0af579b'	System	24 Sep 2020 19:39:16
User entered 'None (1)'	System	24 Sep 2020 19:39:16

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '863bf179-07dc-4379-9f63-9fd2c0af579b' User entered '24 Sep 2020 15:39'	System	24 Sep 2020 19:39:16
	System	24 Sep 2020 19:39:16

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 4'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f4b0b8f2-dd03-4e02-8004-728a26826cee' User entered 'None (1)'	System	26 Sep 2020 03:51:20
	System	26 Sep 2020 03:51:20

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f4b0b8f2-dd03-4e02-8004-728a26826cee' User entered 'No (N)'	System	26 Sep 2020 03:51:20
	System	26 Sep 2020 03:51:20

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:14', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f4b0b8f2-dd03-4e02-8004-728a26826cee' User entered 'No (N)'	System	26 Sep 2020 03:51:20
	System	26 Sep 2020 03:51:20

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f4b0b8f2-dd03-4e02-8004-728a26826cee' User entered 'None (1)'	System	26 Sep 2020 03:51:20
	System	26 Sep 2020 03:51:20

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:18', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f4b0b8f2-dd03-4e02-8004-728a26826cee' User entered '25 Sep 2020 23:51'	System	26 Sep 2020 03:51:20
	System	26 Sep 2020 03:51:20

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 5'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:42:21', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '99bacb21-2d67-4a61-ab1b-89b70054a7b6'	System	26 Sep 2020 16:42:29
User entered 'None (1)'	System	26 Sep 2020 16:42:29

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:42:23', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '99bacb21-2d67-4a61-ab1b-89b70054a7b6' User entered 'No (N)'	System	26 Sep 2020 16:42:29
	System	26 Sep 2020 16:42:29

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:42:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '99bacb21-2d67-4a61-ab1b-89b70054a7b6' User entered 'No (N)'	System	26 Sep 2020 16:42:29
	System	26 Sep 2020 16:42:29

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:42:25', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '99bacb21-2d67-4a61-ab1b-89b70054a7b6'	System	26 Sep 2020 16:42:29
User entered 'None (1)'	System	26 Sep 2020 16:42:29

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:42:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '99bacb21-2d67-4a61-ab1b-89b70054a7b6' User entered '26 Sep 2020 12:42'	System	26 Sep 2020 16:42:29
	System	26 Sep 2020 16:42:29

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 6'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9d1a6d67-9d6a-42af-a865-31f92e1ee84a' User entered 'None (1)'	System	27 Sep 2020 16:27:35
	System	27 Sep 2020 16:27:35

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:23', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9d1a6d67-9d6a-42af-a865-31f92e1ee84a' User entered 'No (N)'	System	27 Sep 2020 16:27:35
	System	27 Sep 2020 16:27:35

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9d1a6d67-9d6a-42af-a865-31f92e1ee84a' User entered 'No (N)'	System	27 Sep 2020 16:27:35
	System	27 Sep 2020 16:27:35

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9d1a6d67-9d6a-42af-a865-31f92e1ee84a' User entered 'None (1)'	System	27 Sep 2020 16:27:35
	System	27 Sep 2020 16:27:35

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '9d1a6d67-9d6a-42af-a865-31f92e1ee84a' User entered '27 Sep 2020 12:27'	System	27 Sep 2020 16:27:35
	System	27 Sep 2020 16:27:35

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 7'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '50bbe358-377a-4a9b-87f7-b3300d4a42aa' User entered 'None (1)'	System	28 Sep 2020 16:13:30
	System	28 Sep 2020 16:13:30

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '50bbe358-377a-4a9b-87f7-b3300d4a42aa' User entered 'No (N)'	System	28 Sep 2020 16:13:30
	System	28 Sep 2020 16:13:30

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:25', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '50bbe358-377a-4a9b-87f7-b3300d4a42aa' User entered 'No (N)'	System	28 Sep 2020 16:13:30
	System	28 Sep 2020 16:13:30

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '50bbe358-377a-4a9b-87f7-b3300d4a42aa' User entered 'None (1)'	System	28 Sep 2020 16:13:30
	System	28 Sep 2020 16:13:30

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '50bbe358-377a-4a9b-87f7-b3300d4a42aa' User entered '28 Sep 2020 12:13'	System	28 Sep 2020 16:13:30
	System	28 Sep 2020 16:13:30

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:55', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:17:57', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:03', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:05', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577' User entered 'None (0)'	System	22 Sep 2020 16:18:14
	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:07', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577'	System	22 Sep 2020 16:18:14
User entered 'No (N)'	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T12:18:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '3ff1ea20-e572-40d2-9270-19566514f577'	System	22 Sep 2020 16:18:14
User entered '22 Sep 2020 12:18'	System	22 Sep 2020 16:18:14

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 12:04'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 14:34'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered 'None (0)'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340'	System	22 Sep 2020 22:01:13
User entered 'Some interference with activity (2)'	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:46', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered 'None (0)'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered 'None (0)'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered 'None (0)'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:00:59', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340'	System	22 Sep 2020 22:01:13
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:03', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered 'No (N)'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-22T18:01:08', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '64e4af25-a85e-4d0a-9b3b-78d5d8b67340' User entered '22 Sep 2020 18:01'	System	22 Sep 2020 22:01:13
	System	22 Sep 2020 22:01:13

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '22 Sep 2020 15:29'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 2'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89'	System	24 Sep 2020 19:38:09
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89' User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:44', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89' User entered 'None (0)'	System	24 Sep 2020 19:38:09
	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89' User entered 'None (0)'	System	24 Sep 2020 19:38:09
	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:51', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89'	System	24 Sep 2020 19:38:09
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:01:59', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89'	System	24 Sep 2020 19:38:09
User entered 'Some interference with activity not requiring medical attention (2)'	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:21', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89' User entered 'Yes (Y)'	System	24 Sep 2020 19:38:09
	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-23T12:02:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '6113ec8a-6d72-4b20-9d6c-34a0716ebb89' User entered '23 Sep 2020 12:02'	System	24 Sep 2020 19:38:09
	System	24 Sep 2020 19:38:09

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 3'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:41', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51'	System	24 Sep 2020 19:39:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51'	System	24 Sep 2020 19:39:04
User entered 'Some interference with activity (2)'	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51' User entered 'None (0)'	System	24 Sep 2020 19:39:04
	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:46', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51' User entered 'None (0)'	System	24 Sep 2020 19:39:04
	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51' User entered 'None (0)'	System	24 Sep 2020 19:39:04
	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:38:56', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51'	System	24 Sep 2020 19:39:04
User entered 'No interference with activity (1)'	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:01', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51' User entered 'Yes (Y)'	System	24 Sep 2020 19:39:04
	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-24T15:39:03', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c000b313-1da9-4dfb-bded-0fd5a2cf7a51' User entered '24 Sep 2020 15:39'	System	24 Sep 2020 19:39:04
	System	24 Sep 2020 19:39:04

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 4'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:25', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:27', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:29', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:30', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'None (0)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered 'No (N)'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-25T23:51:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '16a00575-7822-4898-be75-a81218e91fb7' User entered '25 Sep 2020 23:51'	System	26 Sep 2020 03:51:37
	System	26 Sep 2020 03:51:37

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 5'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:40', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51'	System	26 Sep 2020 16:41:53
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:42', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered 'None (0)'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered 'None (0)'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered 'None (0)'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:46', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered 'None (0)'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:47', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered 'None (0)'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51'	System	26 Sep 2020 16:41:53
User entered 'No (N)'	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-26T12:41:51', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e682a5fb-2bb0-4911-b0f3-83eeec6c1c51' User entered '26 Sep 2020 12:41'	System	26 Sep 2020 16:41:53
	System	26 Sep 2020 16:41:53

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 6'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185'	System	27 Sep 2020 16:27:42
User entered 'No interference with activity (1)'	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered 'None (0)'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered 'None (0)'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered 'None (0)'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered 'None (0)'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:37', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered 'None (0)'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185'	System	27 Sep 2020 16:27:42
User entered 'No (N)'	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-27T12:27:40', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f7afd86d-fd24-4d60-94db-c0cc3b1d8185' User entered '27 Sep 2020 12:27'	System	27 Sep 2020 16:27:42
	System	27 Sep 2020 16:27:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	22 Sep 2020 15:49:23
User entered 'Day 7'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'None (0)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:38', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered 'No (N)'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-09-28T12:13:40', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '30fc1d30-c772-45c4-88e5-ccf2dc4ffce7' User entered '28 Sep 2020 12:13'	System	28 Sep 2020 16:13:42
	System	28 Sep 2020 16:13:42

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:49:23

US3742077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:49:23

US3742077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Oct 2020 13:44:09

US3742077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered '29 Sep 2020'	Sherry McCammon (b) (4)	01 Oct 2020 13:44:09

US3742077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	01 Oct 2020 13:44:09

US3742077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:44:09

US3742077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Oct 2020 13:44:15

US3742077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	01 Oct 2020 13:44:15

US3742077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 13:19:37

US3742077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered '6 Oct 2020'	Sherry McCammon (b) (4)	07 Oct 2020 13:19:37

US3742077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	07 Oct 2020 13:19:37

US3742077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered empty.	Sherry McCammon (b) (4)	07 Oct 2020 13:19:37

US3742077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	07 Oct 2020 13:19:50

US3742077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	07 Oct 2020 13:19:50

US3742077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 16:56:35

US3742077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered '13 Oct 2020'	Hassan Haji (b) (4)	13 Oct 2020 16:56:35

US3742077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	13 Oct 2020 16:56:35

US3742077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 16:56:35

US3742077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:57
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 16:56:42

US3742077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	13 Oct 2020 16:56:42

US3742077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:43

US3742077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '20 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:49:43
	(b) (4)	

US3742077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Clinic (Clinic)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:43

US3742077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'VISIT3'	System	20 Oct 2020 16:49:43

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered empty.	System	20 Oct 2020 16:49:50

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01

US3742077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01

US3742077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:59

US3742077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '20 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 16:49:59

US3742077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:50:32

US3742077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '20 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 16:50:32

US3742077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered '10:56'	Kaitlin Mason (b) (4)	20 Oct 2020 16:50:32

US3742077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '20 Oct 2020 10:56'	System	20 Oct 2020 16:50:32

US3742077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:08:39
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:50:46

US3742077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered '1'	System	20 Oct 2020 16:50:46

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 64'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-10-25T11:15:41', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bca35398-6cdf-4a59-9533-c0c432f6381a' User entered 'No (N)'	System	25 Oct 2020 15:15:52
	System	25 Oct 2020 15:15:52

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-10-25T11:15:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bca35398-6cdf-4a59-9533-c0c432f6381a' User entered 'No (N)'	System	25 Oct 2020 15:15:52
	System	25 Oct 2020 15:15:52

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-10-25T11:15:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bca35398-6cdf-4a59-9533-c0c432f6381a' User entered '25 Oct 2020 11:15:48'	System	25 Oct 2020 15:15:52
	System	25 Oct 2020 15:15:52

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 71'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-02T07:58:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dfcd0778-61fb-48c0-b24b-9a65b29169a7'	System	02 Nov 2020 12:58:37
User entered 'No (N)'	System	02 Nov 2020 12:58:37

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-02T07:58:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dfcd0778-61fb-48c0-b24b-9a65b29169a7'	System	02 Nov 2020 12:58:37
User entered 'No (N)'	System	02 Nov 2020 12:58:37

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-02T07:58:35', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dfcd0778-61fb-48c0-b24b-9a65b29169a7' User entered '02 Nov 2020 07:58:35'	System	02 Nov 2020 12:58:37
	System	02 Nov 2020 12:58:37

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered 'Day 78'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-09T13:21:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ab5bd671-f2fe-4a33-9633-66bd1bdd51ea' User entered 'No (N)'	System	09 Nov 2020 18:21:09
	System	09 Nov 2020 18:21:09

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-09T13:21:03', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ab5bd671-f2fe-4a33-9633-66bd1bdd51ea' User entered 'No (N)'	System	09 Nov 2020 18:21:09
	System	09 Nov 2020 18:21:09

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-09T13:21:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ab5bd671-f2fe-4a33-9633-66bd1bdd51ea' User entered '09 Nov 2020 13:21:06'	System	09 Nov 2020 18:21:09
	System	09 Nov 2020 18:21:09

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 15:35:57

US3742077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:17
Data entry locked.	System	25 Aug 2020 15:35:57
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 15:35:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-21T21:17:08', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '45a94867-4c21-493e-90b6-69400f5a4eb5' User entered 'No (N)'	System	22 Nov 2020 02:17:19
	System	22 Nov 2020 02:17:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-21T21:17:10', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '45a94867-4c21-493e-90b6-69400f5a4eb5' User entered 'No (N)'	System	22 Nov 2020 02:17:19
	System	22 Nov 2020 02:17:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-21T21:17:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '45a94867-4c21-493e-90b6-69400f5a4eb5' User entered '21 Nov 2020 21:17:13'	System	22 Nov 2020 02:17:19
	System	22 Nov 2020 02:17:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-26T12:54:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dea655ed-7f9c-4618-9925-c4831e40920e' User entered 'No (N)'	System	26 Nov 2020 17:54:38
	System	26 Nov 2020 17:54:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-26T12:54:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dea655ed-7f9c-4618-9925-c4831e40920e' User entered 'No (N)'	System	26 Nov 2020 17:54:38
	System	26 Nov 2020 17:54:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-11-26T12:54:35', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'dea655ed-7f9c-4618-9925-c4831e40920e' User entered '26 Nov 2020 12:54:35'	System	26 Nov 2020 17:54:38
	System	26 Nov 2020 17:54:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-04T20:34:30', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1c7da308-13ec-44ef-8b52-45789f83e16b' User entered 'No (N)'	System	05 Dec 2020 01:34:39
	System	05 Dec 2020 01:34:39

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-04T20:34:32', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1c7da308-13ec-44ef-8b52-45789f83e16b' User entered 'No (N)'	System	05 Dec 2020 01:34:39
	System	05 Dec 2020 01:34:39

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-04T20:34:36', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '1c7da308-13ec-44ef-8b52-45789f83e16b' User entered '04 Dec 2020 20:34:36'	System	05 Dec 2020 01:34:39
	System	05 Dec 2020 01:34:39

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-10T10:28:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bd1f098c-faa6-4a1c-8e0a-6aa010e5cddd' User entered 'No (N)'	System	10 Dec 2020 15:28:19
	System	10 Dec 2020 15:28:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-10T10:28:12', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bd1f098c-faa6-4a1c-8e0a-6aa010e5cddd' User entered 'No (N)'	System	10 Dec 2020 15:28:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-10T10:28:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'bd1f098c-faa6-4a1c-8e0a-6aa010e5cddd' User entered '10 Dec 2020 10:28:16'	System	10 Dec 2020 15:28:19
	System	10 Dec 2020 15:28:19

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-17T20:48:37', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4151a0bf-5851-44b3-a87d-128cbf544fa0'	System	18 Dec 2020 01:48:45
User entered 'No (N)'	System	18 Dec 2020 01:48:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-17T20:48:39', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4151a0bf-5851-44b3-a87d-128cbf544fa0' User entered 'No (N)'	System	18 Dec 2020 01:48:45
	System	18 Dec 2020 01:48:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-17T20:48:41', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '4151a0bf-5851-44b3-a87d-128cbf544fa0' User entered '17 Dec 2020 20:48:41'	System	18 Dec 2020 01:48:45
	System	18 Dec 2020 01:48:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-24T20:23:13', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'b744d454-60f8-4f86-bfac-852713e37a87'	System	25 Dec 2020 01:23:24
User entered 'No (N)'	System	25 Dec 2020 01:23:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-24T20:23:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'b744d454-60f8-4f86-bfac-852713e37a87'	System	25 Dec 2020 01:23:24
User entered 'No (N)'	System	25 Dec 2020 01:23:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-24T20:23:21', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'b744d454-60f8-4f86-bfac-852713e37a87' User entered '24 Dec 2020 20:23:21'	System	25 Dec 2020 01:23:24
	System	25 Dec 2020 01:23:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-31T09:50:11', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cbbf0d2b-0aae-4cd0-bdc0-e649229b1622'	System	31 Dec 2020 14:50:20
User entered 'No (N)'	System	31 Dec 2020 14:50:20

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-31T09:50:15', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cbbf0d2b-0aae-4cd0-bdc0-e649229b1622'	System	31 Dec 2020 14:50:20
User entered 'No (N)'	System	31 Dec 2020 14:50:20

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2020-12-31T09:50:18', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'cbbf0d2b-0aae-4cd0-bdc0-e649229b1622' User entered '31 Dec 2020 09:50:18'	System	31 Dec 2020 14:50:20
	System	31 Dec 2020 14:50:20

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-07T20:50:45', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7579edba-ee8b-4c6f-b073-f6580a5d8fac'	System	08 Jan 2021 01:51:09
User entered 'No (N)'	System	08 Jan 2021 01:51:09

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-07T20:50:48', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7579edba-ee8b-4c6f-b073-f6580a5d8fac'	System	08 Jan 2021 01:51:09
User entered 'No (N)'	System	08 Jan 2021 01:51:09

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-07T20:50:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '7579edba-ee8b-4c6f-b073-f6580a5d8fac' User entered '07 Jan 2021 20:50:50'	System	08 Jan 2021 01:51:09

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-14T05:05:56', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'd6d4e279-69a5-4b6b-b824-d9ea2add219c'	System	16 Jan 2021 23:09:57
User entered 'No (N)'	System	16 Jan 2021 23:09:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-14T05:05:58', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'd6d4e279-69a5-4b6b-b824-d9ea2add219c'	System	16 Jan 2021 23:09:57
User entered 'No (N)'	System	16 Jan 2021 23:09:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-14T05:06:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'd6d4e279-69a5-4b6b-b824-d9ea2add219c' User entered '14 Jan 2021 05:06:00'	System	16 Jan 2021 23:09:57
	System	16 Jan 2021 23:09:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-21T00:05:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'daae4012-f7d1-4f6c-8ae6-37e7c3b89e0f' User entered 'No (N)'	System	23 Jan 2021 23:44:05
	System	23 Jan 2021 23:44:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-21T00:05:31', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'daae4012-f7d1-4f6c-8ae6-37e7c3b89e0f' User entered 'No (N)'	System	23 Jan 2021 23:44:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-21T00:05:34', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'daae4012-f7d1-4f6c-8ae6-37e7c3b89e0f' User entered '21 Jan 2021 00:05:34'	System	23 Jan 2021 23:44:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-28T12:25:22', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a0510691-6c2d-4154-b85a-7719e6577755'	System	28 Jan 2021 17:25:29
User entered 'No (N)'	System	28 Jan 2021 17:25:29

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-28T12:25:24', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a0510691-6c2d-4154-b85a-7719e6577755'	System	28 Jan 2021 17:25:29
User entered 'No (N)'	System	28 Jan 2021 17:25:29

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-01-28T12:25:26', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'a0510691-6c2d-4154-b85a-7719e6577755'	System	28 Jan 2021 17:25:29
User entered '28 Jan 2021 12:25:26'	System	28 Jan 2021 17:25:29

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-04T08:43:16', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '0a4cbde9-00f9-4c58-ad65-d62a77f72338'	System	04 Feb 2021 13:43:24
User entered 'No (N)'	System	04 Feb 2021 13:43:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-04T08:43:18', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '0a4cbde9-00f9-4c58-ad65-d62a77f72338'	System	04 Feb 2021 13:43:24
User entered 'No (N)'	System	04 Feb 2021 13:43:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-04T08:43:21', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '0a4cbde9-00f9-4c58-ad65-d62a77f72338' User entered '04 Feb 2021 08:43:21'	System	04 Feb 2021 13:43:24
	System	04 Feb 2021 13:43:24

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-11T07:13:43', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e6cb2a8b-9321-444e-ad6e-785c8a64b014'	System	11 Feb 2021 12:13:51
User entered 'No (N)'	System	11 Feb 2021 12:13:51

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-11T07:13:46', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e6cb2a8b-9321-444e-ad6e-785c8a64b014' User entered 'No (N)'	System	11 Feb 2021 12:13:51
	System	11 Feb 2021 12:13:51

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-11T07:13:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'e6cb2a8b-9321-444e-ad6e-785c8a64b014' User entered '11 Feb 2021 07:13:49'	System	11 Feb 2021 12:13:51
	System	11 Feb 2021 12:13:51

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-18T15:36:49', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f313a6c6-ecf2-49c6-b2cb-cf2d9762db22'	System	18 Feb 2021 20:36:57
User entered 'No (N)'	System	18 Feb 2021 20:36:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-18T15:36:50', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f313a6c6-ecf2-49c6-b2cb-cf2d9762db22'	System	18 Feb 2021 20:36:57
User entered 'No (N)'	System	18 Feb 2021 20:36:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-18T15:36:53', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f313a6c6-ecf2-49c6-b2cb-cf2d9762db22'	System	18 Feb 2021 20:36:57
User entered '18 Feb 2021 15:36:53'	System	18 Feb 2021 20:36:57

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-25T09:20:53', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ed635483-785c-48e9-89ea-1a93006b474b' User entered 'No (N)'	System	25 Feb 2021 14:21:06
	System	25 Feb 2021 14:21:06

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-25T09:20:56', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ed635483-785c-48e9-89ea-1a93006b474b'	System	25 Feb 2021 14:21:06
User entered 'No (N)'	System	25 Feb 2021 14:21:06

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-25T09:21:02', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ed635483-785c-48e9-89ea-1a93006b474b' User entered '25 Feb 2021 09:21:02'	System	25 Feb 2021 14:21:06
	System	25 Feb 2021 14:21:06

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-04T07:06:28', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '582331ac-46fc-440f-9008-48e169c54e32'	System	04 Mar 2021 12:06:38
User entered 'No (N)'	System	04 Mar 2021 12:06:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-04T07:06:30', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '582331ac-46fc-440f-9008-48e169c54e32'	System	04 Mar 2021 12:06:38
User entered 'No (N)'	System	04 Mar 2021 12:06:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-04T07:06:33', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '582331ac-46fc-440f-9008-48e169c54e32' User entered '04 Mar 2021 07:06:33'	System	04 Mar 2021 12:06:38
	System	04 Mar 2021 12:06:38

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-11T09:21:13-05:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f6a2e003-278a-4def-adb4-41f915b523e3'	System	11 Mar 2021 14:21:21
User entered 'No (N)'	System	11 Mar 2021 14:21:21

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-11T09:21:14-05:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f6a2e003-278a-4def-adb4-41f915b523e3'	System	11 Mar 2021 14:21:21
User entered 'No (N)'	System	11 Mar 2021 14:21:21

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-11T09:21:17-05:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'f6a2e003-278a-4def-adb4-41f915b523e3' User entered '11 Mar 2021 09:21:17'	System	11 Mar 2021 14:21:21
	System	11 Mar 2021 14:21:21

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-18T09:30:25-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '66069979-28ca-4319-b7ee-dbc4c5a487a5'	System	18 Mar 2021 13:30:45
User entered 'No (N)'	System	18 Mar 2021 13:30:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-18T09:30:26-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '66069979-28ca-4319-b7ee-dbc4c5a487a5'	System	18 Mar 2021 13:30:45
User entered 'No (N)'	System	18 Mar 2021 13:30:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-18T09:30:29-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '66069979-28ca-4319-b7ee-dbc4c5a487a5'	System	18 Mar 2021 13:30:45
User entered '18 Mar 2021 09:30:29'	System	18 Mar 2021 13:30:45

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-25T08:52:25-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '04796999-619b-4715-81a8-809fb9ab5bb1'	System	25 Mar 2021 12:52:40
User entered 'No (N)'	System	25 Mar 2021 12:52:40

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-25T08:52:26-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '04796999-619b-4715-81a8-809fb9ab5bb1'	System	25 Mar 2021 12:52:40
User entered 'No (N)'	System	25 Mar 2021 12:52:40

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-03-25T08:52:29-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '04796999-619b-4715-81a8-809fb9ab5bb1' User entered '25 Mar 2021 08:52:29'	System	25 Mar 2021 12:52:40
	System	25 Mar 2021 12:52:40

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-01T08:26:56-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8ee4460a-a34d-4929-a446-a191083f0d76' User entered 'No (N)'	System	01 Apr 2021 12:27:03
	System	01 Apr 2021 12:27:03

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-01T08:26:58-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8ee4460a-a34d-4929-a446-a191083f0d76' User entered 'No (N)'	System	01 Apr 2021 12:27:03

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-01T08:27:00-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8ee4460a-a34d-4929-a446-a191083f0d76'	System	01 Apr 2021 12:27:03
User entered '01 Apr 2021 08:27:00'	System	01 Apr 2021 12:27:03

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-08T12:29:00-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '72769641-a632-4724-a5bf-e6e000b8c6a7' User entered 'No (N)'	System	08 Apr 2021 16:29:10
	System	08 Apr 2021 16:29:10

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-08T12:29:02-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '72769641-a632-4724-a5bf-e6e000b8c6a7'	System	08 Apr 2021 16:29:10
User entered 'No (N)'	System	08 Apr 2021 16:29:10

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-08T12:29:04-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '72769641-a632-4724-a5bf-e6e000b8c6a7'	System	08 Apr 2021 16:29:10
User entered '08 Apr 2021 12:29:04'	System	08 Apr 2021 16:29:10

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-15T08:08:58-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ae0b81a8-683c-40b1-8a17-38580c970bb8'	System	15 Apr 2021 12:09:05
User entered 'No (N)'	System	15 Apr 2021 12:09:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-15T08:09:00-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ae0b81a8-683c-40b1-8a17-38580c970bb8'	System	15 Apr 2021 12:09:05
User entered 'No (N)'	System	15 Apr 2021 12:09:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-15T08:09:02-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'ae0b81a8-683c-40b1-8a17-38580c970bb8'	System	15 Apr 2021 12:09:05
User entered '15 Apr 2021 08:09:02'	System	15 Apr 2021 12:09:05

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-22T09:24:03-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c085c81b-b086-4311-91ad-f084917f58d6'	System	22 Apr 2021 13:24:12
User entered 'No (N)'	System	22 Apr 2021 13:24:12

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-22T09:24:06-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c085c81b-b086-4311-91ad-f084917f58d6' User entered 'No (N)'	System	22 Apr 2021 13:24:12
	System	22 Apr 2021 13:24:12

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-22T09:24:08-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c085c81b-b086-4311-91ad-f084917f58d6'	System	22 Apr 2021 13:24:12
User entered '22 Apr 2021 09:24:08'	System	22 Apr 2021 13:24:12

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-29T14:01:17-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c019b929-47b7-46da-b9bc-bcb4903cdc79' User entered 'No (N)'	System	29 Apr 2021 18:01:37

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

Have you been exposed to someone with 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 (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-29T14:01:31-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c019b929-47b7-46da-b9bc-bcb4903cdc79'	System	29 Apr 2021 18:01:37
User entered 'No (N)'	System	29 Apr 2021 18:01:37

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-04-29T14:01:34-04:00', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: 'c019b929-47b7-46da-b9bc-bcb4903cdc79'	System	29 Apr 2021 18:01:37
User entered '29 Apr 2021 14:01:34'	System	29 Apr 2021 18:01:37

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:15:23

US3742077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:23
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:15:23

US3742077

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:34

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 20:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-28T14:48:04', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8f9efffd-1fe6-40da-9843-097a639849d3'	System	28 Feb 2021 19:48:20
User entered 'Yes (Y)'	System	28 Feb 2021 19:48:20

US3742077

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:34

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 20:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-28T14:48:06', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8f9efffd-1fe6-40da-9843-097a639849d3'	System	28 Feb 2021 19:48:20
User entered 'Yes (Y)'	System	28 Feb 2021 19:48:20

US3742077

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:31:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1879BBA6-8559-40E4-93A2-C8EAD691CD88)', Time: '2021-02-28T14:48:09', User OID: 'PatientReportedOutcome (US3742077)', ODM File OID: '8f9efffd-1fe6-40da-9843-097a639849d3' User entered '28 Feb 2021 14:48:09'	System	28 Feb 2021 19:48:20
	System	28 Feb 2021 19:48:20

US3742077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 17:47:19

US3742077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '17 Nov 2020'	Hassan Haji (b) (4)	17 Nov 2020 17:47:19

US3742077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	17 Nov 2020 17:47:19

US3742077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Hassan Haji (b) (4)	17 Nov 2020 17:47:19

US3742077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 17:47:24

US3742077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:01
User entered 'I'	System	17 Nov 2020 17:47:24

US3742077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Dec 2020 19:28:29
	(b) (4)	

US3742077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '21 Dec 2020'	Sherry McCammon (b) (4)	22 Dec 2020 19:28:29
	(b) (4)	

US3742077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Dec 2020 19:28:29
	(b) (4)	

US3742077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:28:29
	(b) (4)	

US3742077

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Dec 2020 19:28:40
	(b) (4)	

US3742077

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User entered 'I'	System	22 Dec 2020 19:28:40

US3742077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 19:43:32
	(b) (4)	

US3742077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '21 Jan 2021'	Sherry McCammon (b) (4)	25 Jan 2021 19:43:32
	(b) (4)	

US3742077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Jan 2021 19:43:32
	(b) (4)	

US3742077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 19:43:32
	(b) (4)	

US3742077

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 19:43:50
	(b) (4)	

US3742077

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User entered 'I'	System	25 Jan 2021 19:43:50

US3742077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 16:49:55
	(b) (4)	

US3742077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '19 Feb 2021'	Sherry McCammon (b) (4)	22 Feb 2021 16:49:55
	(b) (4)	

US3742077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Feb 2021 16:49:55
	(b) (4)	

US3742077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 16:49:55
	(b) (4)	

US3742077

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 16:50:01
	(b) (4)	

US3742077

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:55
User entered 'I'	System	22 Feb 2021 16:50:01

US3742077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:47:54

US3742077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 15:47:54

US3742077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[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 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 15:47:54

US3742077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered 'VISIT4'	System	24 Mar 2021 15:47:54

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered empty.	System	30 Mar 2021 19:19:43

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered empty.	System	30 Mar 2021 19:19:43

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered empty.	System	30 Mar 2021 19:19:43

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered empty.	System	30 Mar 2021 19:19:43

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 19:19:43
	(b) (4)	

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered empty.	System	30 Mar 2021 19:19:43

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58

US3742077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58

US3742077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 15:48:06

US3742077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 15:48:06

US3742077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:49:07

US3742077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 15:49:07

US3742077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered '09:31'	(b) (4), (b) (6)	24 Mar 2021 15:49:07

US3742077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered '24 Mar 2021 09:31'	System	24 Mar 2021 15:49:07

US3742077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:49:17

US3742077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:10:58
User entered '1'	System	24 Mar 2021 15:49:17

US3742077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:13:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:55:34

US3742077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:13:55
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:55:34

US3742077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:13:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:55:34

US3742077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:13:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:55:34

US3742077

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	22 Apr 2021 15:13:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:55:38

US3742077

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 14:55:38

US3742077

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:02:33

US3742077

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:02:33

US3742077

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[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 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:02:33

US3742077

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 19:02:33

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:36:38
User entered '8 Feb 2021' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Apr 2021 16:36:49
Signature has been broken.	Sherry McCammon (b) (4)	12 Apr 2021 16:36:42
User entered '8 Jan 2021' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Apr 2021 16:36:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '6 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:13

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:13

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered empty.	System	08 Feb 2021 19:04:49

US3742077

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered empty.	System	08 Feb 2021 19:04:49

US3742077

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:37

US3742077

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:37

US3742077

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '09:07'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:37

US3742077

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '8 Feb 2021 09:07'	System	08 Feb 2021 19:03:37

US3742077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:58

US3742077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:58

US3742077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '09:12'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:03:58

US3742077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:31:17
User entered '8 Feb 2021 09:12'	System	08 Feb 2021 19:03:58

US3742077

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Oct 2020 13:45:02

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:38:28
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:30:49
User entered	System	30 Nov 2020 20:30:44
'USA-US127-2020-mRNA-1273-P301000010'		
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 20:30:44

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Lip angioedema - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 15:22:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 15:22:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:38:30
User closed query 'Per CDM: Response noted, however please update the specific body location(Angioedema of the lips)in the field location rather than in the answered location.Please update accordingly' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:53:07
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 10:11:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 10:11:55
Data point term sent to Coder	System	30 Nov 2020 20:15:00
Query 'Per CDM: Response noted, however please update the specific body location(Angioedema of the lips)in the field location rather than in the answered location.Please update accordingly' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	30 Nov 2020 20:14:35
Coding entries removed.	Kaitlin Mason (b) (4)	30 Nov 2020 20:14:28
User entered 'ANGIOEDEMA [lips]' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Nov 2020 20:14:28
User opened query 'Per CDM: Response noted, however please update the specific body location(Angioedema of the lips)in the field location rather than in the answered location.Please update accordingly' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:08:18

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate or if cause is unknown, update to reflect the specific body location. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:02:55
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate or if cause is unknown, update to reflect the specific body location. Please reconcile with Con Med eCRF as applicable.	(b) (4), (b) (6)	03 Nov 2020 16:17:01
' answered with 'Angioedema of the lips ' (Site from DM).		
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate or if cause is unknown, update to reflect the specific body location. Please reconcile with Con Med eCRF as applicable.	(b) (4), (b) (6)	03 Nov 2020 05:43:13
' (Site from DM).		
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:48:50
Data point term sent to Coder	System	01 Oct 2020 13:47:50
User entered 'ANGIOEDEMA'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:49:21
User closed query 'Please verify this should be yes since patient saw physician and was prescribed medication for AE.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:49:16
Query 'Please verify this should be yes since patient saw physician and was prescribed medication for AE.' answered with 'participant only took OTC medication. Texted with PI.' (Site from CRA).	Kaitlin Mason (b) (4)	09 Dec 2020 18:49:09
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 18:39:07
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:38:33
User opened query 'Please verify this should be yes since patient saw physician and was prescribed medication for AE.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:37:10
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:29:25
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 20:13:32
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 20:13:25
User entered 'No (N)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 20:13:25
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 12:14:51
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:38:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 01:05:53
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:38:38
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:38:41
User entered '23 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:38:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 14:47:33
Query 'Data is required. Please provide.' answered with 'NO TIME PROVIDED' (Site from System).	Sherry McCammon (b) (4)	01 Oct 2020 13:48:33
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:47:22
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:38:51
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:38:53
User entered '25 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:38:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 14:47:39
Query 'Data is required. Please provide.' answered with 'NO TIME PROVIDED' (Site from System).	Sherry McCammon (b) (4)	01 Oct 2020 13:48:40
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	01 Oct 2020 13:47:22
	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:38:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:39:00
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Nov 2020 13:48:33
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Nov 2020 13:45:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 13:45:05
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '1' reason for change: New Information	Sherry McCammon (b) (4)	25 Nov 2020 13:48:33
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered 'Related (RELATED)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	25 Nov 2020 13:45:05
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered 'I'	Sherry McCammon (b) (4)	01 Oct 2020 13:47:22
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:49:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:39:14
User closed query 'PV Query: Please provide dates of cosmetic filler uses. Products used, application/injection sites, start date, dates of repeat dosing with same our different cosmetic injection products.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:14:03
Query 'PV Query: Please provide dates of cosmetic filler uses. Products used, application/injection sites, start date, dates of repeat dosing with same our different cosmetic injection products.' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	08 Dec 2020 17:59:58
User entered 'SUSAR SYNOPSIS 24 NOVEMBER 2020 – KAREN KOTLOFF MD VOLUNTEER US3742077 DEVELOPED FEVER 10 HOURS AFTER HER SECOND DOSE OF STUDY DRUG (MAX 103.1), ACCOMPANIED BY CHILLS (GRADE 2), HEADACHE AND FATIGUE (GRADE 3), AND NAUSEA (GRADE 1). THE FOLLOWING MORNING SHE AWOKE WITH SEVERE ANGIOEDEMA WITHOUT HIVES, RASH, TONGUE OR MOUTH SWELLING, DYSPHAGIA, DYSPNEA, WHEEZE, OR STRIDOR. THAT DAY SHE ALSO COMPLAINED OF PAINFUL MUSCLES IN THE BACK OF HER NECK MENTAL FOGGINESS. ALL SYMPTOMS RESOLVED WITHIN 48 HOURS. SHE HAD SIMILAR ANGIOEDEMA FOLLOWING A FLU VACCINE APPROXIMATELY ONE YEAR AGO. SHE HAS NO KNOWN ALLERGIES OR FAMILY HISTORY OF ANGIOEDEMA. SHE WAS TREATED WITH TYLENOL FOR FEVER AND HEADACHE, BENADRYL, AND FAMOTIDINE. PARTICIPANT REPORTS PREVIOUS HISTORY OF RECEIVING Restylane INJECTIONS IN HER LIPS on 03 May 2019.' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	08 Dec 2020 17:59:52

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide dates of cosmetic filler uses. Products used, application/injection sites, start date, dates of repeat dosing with same our different cosmetic injection products.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 23:35:30
User entered 'SUSAR Synopsis 24 November 2020 – Karen Kotloff MD Volunteer US3742077 developed fever 10 hours after her second dose of study drug (max 103.1), accompanied by chills (grade 2), headache and fatigue (grade 3), and nausea (grade 1). The following morning she awoke with severe angioedema without hives, rash, tongue or mouth swelling, dysphagia, dyspnea, wheeze, or stridor. That day she also complained of painful muscles in the back of her neck mental foggiess. All symptoms resolved within 48 hours. She had similar angioedema following a flu vaccine approximately one year ago. She has no known allergies or family history of angioedema. She was treated with Tylenol for fever and headache, benadryl, and famotidine. Participant reports previous history of receiving Juvederm injections in her lips.' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 01:05:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 13:45:05
User entered '0'	System	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 13:47:22

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as SOC: Psychiatric disorders, HLGT: Adjustment disorders (incl subtypes), HLT: Adjustment disorders, PT: Adjustment disorder with depressed mood, LLT: Situational depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Dec 2020 19:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:28:54
Data point term sent to Coder	System	22 Dec 2020 19:27:47
User entered 'SITUATIONAL DEPRESSION'	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 22:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Jan 2021 22:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 22:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	27 Jan 2021 22:07:01
User entered '15 Sep 2020' reason for change: Data Entry Error	System	27 Jan 2021 22:07:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	27 Jan 2021 22:04:04
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 22:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered '15 Sep 2020' (non-conformant).	System	27 Jan 2021 22:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User entered empty.	System	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:24
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:51:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:51:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'per MM: please provide the end date' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:45:58
Query 'per MM: please provide the end date' answered with 'ongoing' (Site from DM).	Kaitlin Mason (b) (4)	03 Feb 2021 17:13:38
User opened query 'per MM: please provide the end date' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:28:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:28:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	22 Dec 2020 19:28:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:24
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Mar 2021 15:57:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Mar 2021 15:57:45
Signature has been broken.	System	24 Mar 2021 15:51:34
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:51:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User entered empty.	System	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'No (N)' reason for change: Data Entry Error	System	27 Jan 2021 22:04:04
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Jan 2021 22:04:04
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Jan 2021 22:04:04
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18
	(b) (4)	

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 22:04:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	27 Jan 2021 22:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:27:18
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM: 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.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 07:24:00
' (Site from DM). Query 'Per DM: 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.	Kaitlin Mason (b) (4) (b) (4)	12 Feb 2021 15:50:48
' answered with 'conmed #8' (Site from DM). User opened query 'Per DM: 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.	(b) (4), (b) (6)	05 Feb 2021 15:05:16
' (Site from DM). User entered 'I'	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:24
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:57:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:57:45
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:00:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:27:18

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User entered '0'	System	27 Jan 2021 22:04:04

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28
User entered 'I'	System	27 Jan 2021 22:04:04

US3742077

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:31:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:28

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'tylenol taken ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:36:51
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	10 Feb 2021 21:25:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 13:34:09
	(b) (4), (b) (6)	08 Sep 2020 15:03:48

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: DROSPIRENONE;ETHINYLESTRADIOL, PRODUCTSYNONYM: DROSPIRENONE AND ETHINYL ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:09:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:09:44
Data point term sent to Coder	System	08 Sep 2020 15:08:52
User entered 'Drospirenone Ethinyl Estradiol'	(b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 15:53:45
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Birth Control'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:37:11
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Kindly check decimal places for the second dose. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:37:05
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	10 Feb 2021 21:23:52
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Kindly check decimal places for the second dose. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	10 Feb 2021 21:23:48
User entered '3/0.02' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	10 Feb 2021 21:22:42
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:46:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Kindly check decimal places for the second dose. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:46:33
User entered '3mg/0.002mg'	(b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:08:44

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 15:20:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:20:43
Data point term sent to Coder	System	08 Sep 2020 15:20:17
User entered 'Tylenol'	(b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Pain at vaccination site'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '650'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User entered '1'	System	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User entered '1'	System	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:32
User entered '804 (804)'	System	08 Sep 2020 15:20:13

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:55:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:55:18
Data point term sent to Coder	System	01 Oct 2020 13:53:58
User entered 'TYLENOL'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
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)	01 Dec 2020 15:20:58
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 'does not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 17:58:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[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)	13 Nov 2020 00:47:38
User entered 'FEVER REACTOGENCITY'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'I'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'g (g)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '23 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '24 Sep 2020'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User entered '1'	System	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User entered '1'	System	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:03
User entered '804 (804)'	System	01 Oct 2020 13:53:40

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 17:33:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:33:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:06
Data point term sent to Coder User entered 'BENADRYL'	System Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:56:02 01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'ANGIOEDEMA'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '25'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mg (mg)'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '23 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 13:21:28
User entered '26 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Oct 2020 13:21:28
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 13:55:16
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User entered empty.	System	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User entered empty.	System	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:55
User entered empty.	System	01 Oct 2020 13:55:16

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:57:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:57:54
Data point term sent to Coder User entered 'FAMOTIDINE'	System Sherry McCammon (b) (4)	01 Oct 2020 13:57:03 01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:20:03
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Used to mitigate systemic inflammatory reaction' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 18:00:39
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:45:49
User entered 'ANGIOEDEMA'	Sherry McCammon (b) (4) (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '20'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mg (mg)'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'twice daily (BID)'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '23 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 13:21:48
User entered '26 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	07 Oct 2020 13:21:48
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 13:56:23
User entered empty.	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User entered '2'	System	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User entered '1'	System	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:51
User entered '804 (804)'	System	01 Oct 2020 13:56:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
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)	20 Oct 2020 16:50:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 16:50:36
Data point term sent to Coder	System	20 Oct 2020 16:49:31
User entered 'FLU VACCINE'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'FLU PREVENTION'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0.5'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mL (mL)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'once (ONCE)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '14 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '14 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User entered empty.	System	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User entered empty.	System	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:37
User entered empty.	System	20 Oct 2020 16:48:55

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
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 ACNE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:37:36
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 ACNE should be recorded, and update con med indication or provide clarification. ' answered with 'per dermatologist direction ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	10 Feb 2021 21:24:19
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 ACNE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:45:42
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.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:46:48
Data point term sent to Coder	System	17 Nov 2020 17:45:50
User entered 'doxycycline'	Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:34:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated mh' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 20:27:37
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 02:33:10
User entered 'acne'	Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '100'	Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'twice daily (BID)'	Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered empty.	(b) (4) Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '13 Nov 2020'	(b) (4) Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '0'	Hassan Haji (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	22 Feb 2021 16:51:22
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 17:45:23
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	22 Feb 2021 16:51:22
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	17 Nov 2020 17:45:23
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User entered '2'	System	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User entered '1'	System	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:42
User entered '804 (804)'	System	17 Nov 2020 17:45:23

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Dec 2020 20:18:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:18:47
Data point term sent to Coder	System	22 Dec 2020 19:32:53
User entered 'WELLBUTRIN'	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 19:32:41

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'SITUATIONAL DEPRESSION'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '300'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '04 Dec 2020'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:41:21
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Participant continues conmed' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 19:22:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:34:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	22 Dec 2020 19:32:41

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Dec 2020 19:32:41
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 19:32:41

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 19:32:41

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Dec 2020 19:32:41

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 16:53:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:53:01
Data point term sent to Coder	System	22 Feb 2021 16:52:41
User entered 'spironolactone'	Sherry McCammon (b) (4) (b) (4)	22 Feb 2021 16:52:38

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'acne'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '50'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '12 Feb 2021'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Feb 2021 16:52:38
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 16:52:38

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 16:52:38

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 16:52:38

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 22:06:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:06:40
Data point term sent to Coder	System	04 Mar 2021 14:31:50
User entered 'botox'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to forehead'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '25'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'IU (IU)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Mar 2021 13:33:12
Query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:56:59
User opened query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:56:45
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:25:41
Query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Mar 2021 13:33:17
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Mar 2021 13:33:12
User opened query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:57:14
User entered 'units'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:17:06
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Mar 2021 20:17:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	04 Mar 2021 14:31:45
	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN UNK 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN UNK 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered empty.	System	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered empty.	System	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered empty.	System	04 Mar 2021 14:31:45

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
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)	16 Apr 2021 09:28:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:28:54
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: ANTIHIDROTICS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:51:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:51:45
Data point term sent to Coder User entered 'botox injections'	System Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:35:52 04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to forehead'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '15'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Mar 2021 13:33:40
User entered 'Other (OTHER)'	(b) (4)	
	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:26:06
Query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Mar 2021 13:33:45
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Mar 2021 13:33:40
User opened query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:58:07
User entered 'units'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:17:36
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Mar 2021 20:17:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	04 Mar 2021 14:34:54
	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User entered empty.	System	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User entered empty.	System	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:04
User entered empty.	System	04 Mar 2021 14:34:54

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTYLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:36:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:36:10
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTYLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:28:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:28:53
Data point term sent to Coder	System	04 Mar 2021 20:18:32
Data point term sent to Coder	System	04 Mar 2021 14:37:53
User entered 'restylane'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to lips'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'I'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cc'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'x2'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4)	
	System	04 Mar 2021 20:18:03
User entered 'Other (OTHER)' reason for change:	Sherry McCammon (b) (4)	04 Mar 2021 20:18:03
Data Entry Error	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	04 Mar 2021 14:37:34
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'submucosal'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN May 2019'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Oct 2019'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User entered empty.	System	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User entered empty.	System	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:17
User entered empty.	System	04 Mar 2021 14:37:34

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTITLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:38:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:38:47
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTITLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:38:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:38:29
Data point term sent to Coder User entered 'restylane injections'	System Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:40:57 04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to bilateral eyes'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '.5'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cc'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'x2'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'intradermal'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Dec 2019'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Sep 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User entered empty.	System	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User entered empty.	System	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:29
User entered empty.	System	04 Mar 2021 14:40:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID;LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: JUVEDERM ULTRA PLUS XC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:31:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:31:58
Data point term sent to Coder	System	04 Mar 2021 14:43:00
User entered 'juvaderm ultra xc injections'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to lips'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'I'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cc'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	04 Mar 2021 14:42:51
User entered 'other (OTHER)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Mar 2021 14:42:51
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	04 Mar 2021 14:42:15
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '1x'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'intradermal'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Jul 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Jul 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User entered empty.	System	04 Mar 2021 14:42:51
User entered '1'	System	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User entered empty.	System	04 Mar 2021 14:42:51
User entered '1'	System	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:41
User entered empty.	System	04 Mar 2021 14:42:51
User entered '804 (804)'	System	04 Mar 2021 14:42:15

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID;LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: JUVEDERM ULTRA PLUS XC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:31:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:31:57
Data point term sent to Coder	System	04 Mar 2021 14:45:11
User entered 'juvaderm ultra xc'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to naso labial folds bilaterally'	(b) (4) Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'I'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cc'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'x1'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'intradermal'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Jul 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Jul 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User entered empty.	System	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User entered empty.	System	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:53
User entered empty.	System	04 Mar 2021 14:44:52

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTITLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:38:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 10:38:48
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:03:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTITLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:38:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:38:30
Data point term sent to Coder	System	04 Mar 2021 14:48:24
User entered 'restylane lift'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cosmetic to cheeks bilaterally'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'I'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'cc'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:18:39
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Mar 2021 20:18:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	04 Mar 2021 14:47:20
	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20
	(b) (4)	

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'intradermally'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Nov 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered '0'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'UN Nov 2020'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:48
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User entered empty.	System	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User entered empty.	System	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:30:10
User entered empty.	System	04 Mar 2021 14:47:20

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:31:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 17:40:51

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '13 Nov 2020'	Hassan Haji (b) (4)	17 Nov 2020 17:43:02
	(b) (4)	

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
User entered 'microneedling with radiofrequency'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Nov 2020 17:43:02

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'Other (OTHER)'	Hassan Haji (b) (4)	17 Nov 2020 17:43:02
	(b) (4)	

US3742077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered 'acne scarring'	Hassan Haji (b) (4)	17 Nov 2020 17:43:02
	(b) (4)	

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered	System	30 Nov 2020 20:30:44
'USA-US127-2020-MRNA-1273-P301000010'		

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Karen'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Kotloff'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '685 W. Baltimore Street, HSF 480'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Baltimore'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Un-reviewed for Safety.	System	09 Dec 2020 17:14:28
User entered empty.	System	09 Dec 2020 17:14:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'Maryland'	Kaitlin Mason (b) (4)	02 Dec 2020 21:53:34
	(b) (4)	

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '21201'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'US'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '2'	System	09 Dec 2020 17:14:28
User entered '1'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'USA-US127-2020-MRNA-1273-P301000010'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Karen'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Kotloff'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '685 W. Baltimore Street, HSF 480'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Baltimore'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Un-reviewed for Safety.	System	09 Dec 2020 17:14:28
User entered empty.	System	09 Dec 2020 17:14:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'Maryland'	Kaitlin Mason (b) (4)	02 Dec 2020 21:53:34
	(b) (4)	

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '21201'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'US'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '2'	System	09 Dec 2020 17:14:28
User entered '1'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
User entered '30/Nov/2020 15:31'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:34

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.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered	System	30 Nov 2020 20:30:44
'USA-US127-2020-MRNA-1273-P301000010'		

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'No (N)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Yes (Y)'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Karen'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Kotloff'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '685 W. Baltimore Street, HSF 480'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered 'Baltimore'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Un-reviewed for Safety.	System	09 Dec 2020 17:14:28
User entered empty.	System	09 Dec 2020 17:14:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'Maryland'	Kaitlin Mason (b) (4)	02 Dec 2020 21:53:34
	(b) (4)	

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 20:31:09
User entered '21201'	System	30 Nov 2020 20:30:44

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 17:14:15
User entered 'US'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
	(b) (4)	
User entered '2'	System	09 Dec 2020 17:14:28
User entered '1'	System	30 Nov 2020 20:31:16

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:40:34
User entered '09/Dec/2020 17:14'	System	09 Dec 2020 17:14:28

US3742077

Folder: SAE USA-US127-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:34

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.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:40:34
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 17:14:28