

US3742076 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:30:43

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US3742076

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

[Participant ID](#)

US3742076

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

US3742076

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:07:52

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:07:52

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Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN MAR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN MAR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN JUN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Condition	NEOSPORIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3742076

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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)	09:48 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:48
Height (xxx.x)	60.0 in
Weight (xxx.x)	163.5 lb
BMI (xxx.x)	31.99817 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:07:52

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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) 30 JUN 1990

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:07:52

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

What was the participant's randomization number? 187515

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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)	09:48 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:48
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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)	11:56 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 11:56
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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) 11:26 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 11:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

10:29 (24 HR)

Collection date and time (derived)

25 AUG 2020 10:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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	10:40	25 AUG 2020 10:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 25 AUG 2020 11:57

PC Open Date & Time 25 AUG 2020 11:46

PC Close Date & Time 25 AUG 2020 14:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °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	25 AUG 2020 20:30
PC Open Date & Time	25 AUG 2020 15:11
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 20:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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 18:58

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 19:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

96.9 °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

30 AUG 2020 06:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

31 AUG 2020 00:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

31 AUG 2020 19:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 11:58

PC Open Date & Time

25 AUG 2020 11:46

PC Close Date & Time

25 AUG 2020 14:16

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 20:31

PC Open Date & Time

25 AUG 2020 15:11

PC Close Date & Time

26 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 20:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 18:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 19:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

30 AUG 2020 06:55

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 00:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 19:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 11:59
PC Open Date & Time	25 AUG 2020 11:46
PC Close Date & Time	25 AUG 2020 14:16

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 20:32
PC Open Date & Time	25 AUG 2020 15:11
PC Close Date & Time	26 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:59
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 19:47
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 06:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 00:32
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:53
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3742076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742076

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:50

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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)	09:11 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:11
Temperature (xxx.x)	097.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	089 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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)	10:13 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:13
Temperature (xxx.x)	097.1 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)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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.

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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) 09:42 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 09:42

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

US3742076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

09:04 (24 HR)

Collection date and time (derived)

22 SEP 2020 09:04

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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	09:02	22 SEP 2020 09:02
Nasopharyngeal Swab 2	No		

US3742076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

98.1 °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

22 SEP 2020 10:13

PC Open Date & Time

22 SEP 2020 10:02

PC Close Date & Time

22 SEP 2020 12:32

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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 16:42
PC Open Date & Time	22 SEP 2020 13:27
PC Close Date & Time	23 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

23 SEP 2020 21:20

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 09:37

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

25 SEP 2020 17:52

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 07:51

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 18:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 18:44

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

22 SEP 2020 10:14

PC Open Date & Time

22 SEP 2020 10:02

PC Close Date & Time

22 SEP 2020 12:32

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 16:43

PC Open Date & Time

22 SEP 2020 13:27

PC Close Date & Time

23 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 21:20

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 09:37

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 17:52

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 07:51

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 18:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 18:44

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 10:14
PC Open Date & Time	22 SEP 2020 10:02
PC Close Date & Time	22 SEP 2020 12:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 16:43
PC Open Date & Time	22 SEP 2020 13:27
PC Close Date & Time	23 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:21
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 09:38
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 17:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 07:52
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:04
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 ☒

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 18:45
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3742076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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) _____

US3742076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

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.

US3742076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

08:05 (24 HR)

Collection date and time (derived)

20 OCT 2020 08:05

US3742076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:07:52

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 15:56:10

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 09:50:17

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:29:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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	30 NOV 2020 14:14:31
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

05 DEC 2020 15:22:11

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 07:14:43

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 DEC 2020 06:50:26
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 15:49:41

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

02 JAN 2021 09:41:18

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

08 JAN 2021 15:41:53

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 JAN 2021 09:31:28
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

22 JAN 2021 12:13:47

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 07:52:19

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

08 FEB 2021 10:25:05

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 09:49:21

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 10:24:46

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 00:02:37

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 08:38:13

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 11:40:20

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 09:16:42

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 10:45:20

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 08:30:20

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 09:25:46

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 14:04:51

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

26 APR 2021 15:13:56

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 10:42:46

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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="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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 <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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	20 SEP 2021 23:59
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US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 <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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	13 DEC 2021 23:59
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US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 544

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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="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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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°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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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="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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	17 OCT 2022 23:59
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US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:30:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 15:33:25

US3742076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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) _____

US3742076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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.

US3742076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	09:04 (24 HR)
Collection date and time (derived)	01 APR 2021 09:04

US3742076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 17:53:27

Generated On: 10 Jun 2021 09:30:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742076

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 17:53:27

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742076

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:43

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"/>

US3742076

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:30:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742076

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3742076

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	4 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	4 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3742076

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

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

US3742076

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 09:45
Temperature (xxx.x)	098.1 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	062 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 16:57:00

Generated On: 10 Jun 2021 09:30:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 10:28
Temperature (xxx.x)	099.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	065 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3742076

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 FEB 2021

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 09:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3742076

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	4 FEB 2021 09:20

US3742076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

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

Collection date (dd MMM yyyy)	4 FEB 2021
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Collection time (00:00 - 23:59)	09:21
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Collection Date and Time (derived)	4 FEB 2021 09:21
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US3742076

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:00:03

Generated On: 10 Jun 2021 09:30:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:00:03

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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)	4 MAR 2021
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 10:04
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	065 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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)	4 MAR 2021
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 10:46
Temperature (xxx.x)	097.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	067 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

US3742076

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3742076

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:03:44

Generated On: 10 Jun 2021 09:30:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 4 MAR 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 4 MAR 2021 10:15

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

US3742076

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:03:44

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742076

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742076

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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) _____

US3742076

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

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.

US3742076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	09:04 (24 HR)
Collection date and time (derived)	01 APR 2021 09:04

US3742076

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 20:59:01

Generated On: 10 Jun 2021 09:30:43

AEID	USA-US127-2021-MRNA-1273-P30 1000007
Adverse event	WORSENING OSTEOARTHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	15 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 20:59:01

Generated On: 10 Jun 2021 09:30:43

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
VOLUNTEER HAD RIGHT SHOULDER REPLACEMENT ON 12JAN2021 AND WAS HOSPITALIZED UNTIL 15JAN2021.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 20:59:01

Generated On: 10 Jun 2021 09:30:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 20:59:01

Generated On: 10 Jun 2021 09:30:43

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 20:59:01

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

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	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 MAR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	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 MAR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS CORONARY
ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 16:56:59

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	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 type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	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)		10 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)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication POST OP PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

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

EVERY 3 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication OXYCONDONE

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication AMPLODIPINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING HTN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 JAN 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"/>

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE RIGHT
SHOULDER PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

	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)		12 JAN 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 16:56:59

Generated On: 10 Jun 2021 09:30:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 JAN 2021	RIGHT SHOULDER REPLACEMENT FOR WORSENING OSTEOARTHRITIS	Adverse Event	

US3742076

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:30:43

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

US3742076

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:30:43

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 ☐

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 14:27
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

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 11:26
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

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 15:18
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

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	05/MAR/2021 11:46
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

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 07 Apr 2021 21:03:45

Generated On: 10 Jun 2021 09:30:43

SAEID	USA-US127-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 08:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742076 (Prod: University of Maryland School of Medicine)

US3742076

Form: Participant Creation

Generated On: 10 Jun 2021 09:30:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'US3742076'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:39:51

US3742076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 15:13:21

US3742076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:39:52

US3742076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	25 Aug 2020 15:13:21

US3742076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'SCRN'	System	25 Aug 2020 15:13:21

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:39:53

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '76'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'YEARS'	System	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '76'	System	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Female (F)'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'I'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:14:51

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Aug 2020'	System	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2020'	System	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Amendment 3 (3)'	Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:12:38

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:39:52

US3742076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'I'	System	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:30:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 16:50:56

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:06:35
Data point term sent to Coder	System	25 Aug 2020 17:05:18
User entered 'hypothyroidism'	Hassan Haji (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:38:48
User entered '30 Jun 2000'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Jan 2000'	System	09 Sep 2020 13:38:48
User entered 'Jun 2000'	System	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2000'	System	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:05:17

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:35
Data point term sent to Coder	System	25 Aug 2020 17:06:20
User entered 'high cholesterol'	Hassan Haji (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN Mar 2017' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:38:59
User entered '15 Mar 2017'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Mar 2017'	System	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2017'	System	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:06:06

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:35
Data point term sent to Coder	System	25 Aug 2020 17:07:21
User entered 'hypertension'	Hassan Haji (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN Mar 2017' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:11
User entered '15 Mar 2017'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Mar 2017'	System	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2017'	System	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:06:53

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:09:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:09:30
Data point term sent to Coder	System	25 Aug 2020 17:08:27
User entered 'coronary artery disease'	Hassan Haji (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:42
User entered '15 Jun 2017'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Jan 2017'	System	09 Sep 2020 13:39:42
User entered 'Jun 2017'	System	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2017'	System	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:07:47

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:10:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:10:32
Data point term sent to Coder	System	25 Aug 2020 17:09:28
User entered 'osteoarthritis'	Hassan Haji (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:56
User entered '30 Jun 2000'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Jan 2000'	System	09 Sep 2020 13:39:56
User entered 'Jun 2000'	System	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2000'	System	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	25 Aug 2020 17:09:02

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:04:10
Data point term sent to Coder	System	08 Oct 2020 20:07:47
User entered 'menopause'	Hassan Haji (b) (4)	08 Oct 2020 20:07:40
	(b) (4)	

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN Jun 1990'	Hassan Haji (b) (4)	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Jun 1990'	System	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '1990'	System	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	08 Oct 2020 20:07:40

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
Data point term sent to Coder	System	21 Dec 2020 21:04:51
User entered 'NEOSPORIN ALLERGY'	(b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'Jan 2000'	System	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '2000'	System	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered empty.	System	21 Dec 2020 21:04:51

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:48'	Hassan Haji (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered '25 Aug 2020 09:48'	System	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '60.0' in	(b) (4) Hassan Haji (b) (4)	25 Aug 2020 16:53:11
DataPoint set to visible.	(b) (4) System	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '163.5' lb	Hassan Haji (b) (4)	25 Aug 2020 16:53:11
DataPoint set to visible.	System	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
Amendment Manager: User entered '31.99817'	System	17 Sep 2020 00:22:23
User entered '32.0'	System	25 Aug 2020 16:53:11
DataPoint set to visible.	System	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'kg/m2'	System	25 Aug 2020 16:53:11
DataPoint set to visible.	System	25 Aug 2020 15:16:40

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
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 18:47:44
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 V1' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:33:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:33:13
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 18:38:56
User entered '098.2' F	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 16:33:13
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Hassan Haji (b) (4)	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:13
User entered '078'	Kaitlin Mason (b) (4)	25 Aug 2020 16:53:11
	(b) (4)	

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'bpm'	System	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:13
User entered '14'	Kaitlin Mason (b) (4)	25 Aug 2020 16:53:11
	(b) (4)	

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'breaths/min'	System	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:13
User entered '165'	Kaitlin Mason (b) (4)	25 Aug 2020 16:53:11
	(b) (4)	

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'mmHg'	System	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:13
User entered '074'	Kaitlin Mason (b) (4)	25 Aug 2020 16:53:11
	(b) (4)	

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User entered 'mmHg'	System	25 Aug 2020 16:53:11

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32

US3742076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32

US3742076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:17:39

US3742076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:17:39

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
Query 'Per CDM: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.'" canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:27:22
User opened query 'Per CDM: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.'" (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:21:15
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:08:24
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'added' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 13:18:32
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:03:25
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '30 Jun 1990'	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:30:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Hassan Haji (b) (4)	25 Aug 2020 16:55:54

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'I'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	(b) (4) Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '0'	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:03:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	25 Aug 2020 15:19:33

US3742076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:13

US3742076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:13

US3742076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:13

US3742076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'VISIT1'	System	25 Aug 2020 15:15:13

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:59:33

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '187515'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:59:33

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:59:33

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:46

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:46

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:46

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:46

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Aug 2020 15:15:46

US3742076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 16:33:37
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:48:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:48:33

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
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 18:47:37
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 16:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:33:52
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 18:39:02
User entered '60.0' in	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:52
User entered '163.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 17:00:13
	Hassan Haji (b) (4)	
	(b) (4)	

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
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 18:47:37
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 16:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:33:52
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 18:39:02
User entered '60.0' in	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:52
User entered '163.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 17:00:13
	Hassan Haji (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:48'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '25 Aug 2020 09:48'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '098.2' F	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '078'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'bpm'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '14'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'breaths/min'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User closed query 'per CDM: response is noted, however, please indicate whether or not CS or NCS' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:40:48
Query 'per CDM: response is noted, however, please indicate whether or not CS or NCS' answered with 'NCS SYSTOLIC BLOOD PRESSURE WITHIN RANGE' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:32:08
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 14:16:44
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:47:20
User opened query 'per CDM: response is noted, however, please indicate whether or not CS or NCS' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 19:47:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'systolic pressure 165. That is the correct value recorded.' (Site from System).	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:01:30
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Aug 2020 17:00:13
User entered '165'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '078' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:16:44
User entered '074'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
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 18:47:37
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 16:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 16:33:52
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 18:39:02
User entered '60.0' in	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 16:33:52
User entered '163.5' lb	Kaitlin Mason (b) (4)	25 Aug 2020 17:00:13
	Hassan Haji (b) (4)	
	(b) (4)	

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '11:56'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '25 Aug 2020 11:56'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '98.0' F	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Oral (Oral)'	(b) (4) Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '066'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'bpm'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '14'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'breaths/min'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '112'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '074'	Hassan Haji (b) (4)	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	25 Aug 2020 17:00:13

US3742076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
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 18:47:40
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 14:35:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 14:35:22
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 18:39:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:02:12

US3742076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 14:35:22
User entered '25 Aug 2020'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:02:12

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '11:26'	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '25 Aug 2020 11:26'	System	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'ONCE'	System	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 15:31:26

US3742076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:03:17

US3742076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 17:03:17

US3742076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '10:29'	Hassan Haji (b) (4)	25 Aug 2020 17:03:17

US3742076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '25 Aug 2020 10:29'	System	25 Aug 2020 17:03:17

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '25 Aug 2020'	Hassan Haji (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '10:40'	Hassan Haji (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '25 Aug 2020 10:40'	System	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Hassan Haji (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	25 Aug 2020 17:03:32

US3742076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	25 Aug 2020 17:04:03

US3742076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '1'	System	25 Aug 2020 17:04:03

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:57:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b9e0f694-575f-49b9-b618-c78b4d21110a'	System	25 Aug 2020 15:59:39
User entered 'Yes (Y)'	System	25 Aug 2020 15:59:39

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:57:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b9e0f694-575f-49b9-b618-c78b4d21110a' User entered '98.0'	System	25 Aug 2020 15:59:39
	System	25 Aug 2020 15:59:39

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:57:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b9e0f694-575f-49b9-b618-c78b4d21110a'	System	25 Aug 2020 15:59:39
User entered 'No (N)'	System	25 Aug 2020 15:59:39

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:57:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b9e0f694-575f-49b9-b618-c78b4d21110a'	System	25 Aug 2020 15:59:39
User entered '25 Aug 2020 11:57'	System	25 Aug 2020 15:59:39

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 11:46'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 14:16'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:30:26', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2ad76225-f9ec-4fe4-9f90-b36fa6563ccf'	System	26 Aug 2020 00:32:49
User entered 'Yes (Y)'	System	26 Aug 2020 00:32:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:30:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2ad76225-f9ec-4fe4-9f90-b36fa6563ccf' User entered '96.9'	System	26 Aug 2020 00:32:49
	System	26 Aug 2020 00:32:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:30:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2ad76225-f9ec-4fe4-9f90-b36fa6563ccf'	System	26 Aug 2020 00:32:49
User entered 'No (N)'	System	26 Aug 2020 00:32:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:30:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2ad76225-f9ec-4fe4-9f90-b36fa6563ccf'	System	26 Aug 2020 00:32:49
User entered '25 Aug 2020 20:30'	System	26 Aug 2020 00:32:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 15:11'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 2'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'da021c01-4cfc-48a0-83f5-39cc886929db'	System	27 Aug 2020 00:04:20
User entered 'Yes (Y)'	System	27 Aug 2020 00:04:20

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'da021c01-4cfc-48a0-83f5-39cc886929db'	System	27 Aug 2020 00:04:20
User entered '97.8'	System	27 Aug 2020 00:04:20

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:13', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'da021c01-4cfc-48a0-83f5-39cc886929db'	System	27 Aug 2020 00:04:20
User entered 'No (N)'	System	27 Aug 2020 00:04:20

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'da021c01-4cfc-48a0-83f5-39cc886929db'	System	27 Aug 2020 00:04:20
User entered '26 Aug 2020 20:02'	System	27 Aug 2020 00:04:20

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 3'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:58:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99b8e2c3-4f33-4a29-b8ad-6609619c783e'	System	27 Aug 2020 23:00:55
User entered 'Yes (Y)'	System	27 Aug 2020 23:00:55

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:58:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99b8e2c3-4f33-4a29-b8ad-6609619c783e' User entered '96.9'	System	27 Aug 2020 23:00:55
	System	27 Aug 2020 23:00:55

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:58:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99b8e2c3-4f33-4a29-b8ad-6609619c783e'	System	27 Aug 2020 23:00:55
User entered 'No (N)'	System	27 Aug 2020 23:00:55

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-27T18:58:54', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99b8e2c3-4f33-4a29-b8ad-6609619c783e'	System	27 Aug 2020 23:00:55
User entered '27 Aug 2020 18:58'	System	27 Aug 2020 23:00:55

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 4'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'eef44cf4-f56b-46c9-9049-23c7aef72991'	System	28 Aug 2020 23:48:28
User entered 'Yes (Y)'	System	28 Aug 2020 23:48:28

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'eef44cf4-f56b-46c9-9049-23c7aef72991'	System	28 Aug 2020 23:48:28
User entered '96.9'	System	28 Aug 2020 23:48:28

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:20', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'eef44cf4-f56b-46c9-9049-23c7aef72991'	System	28 Aug 2020 23:48:28
User entered 'No (N)'	System	28 Aug 2020 23:48:28

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-28T19:46:26', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'eef44cf4-f56b-46c9-9049-23c7aef72991'	System	28 Aug 2020 23:48:28
User entered '28 Aug 2020 19:46'	System	28 Aug 2020 23:48:28

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 5'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:54:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b7afec13-92a1-477e-859b-371489cb2434'	System	30 Aug 2020 10:58:17
User entered 'Yes (Y)'	System	30 Aug 2020 10:58:17

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:54:47', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b7afec13-92a1-477e-859b-371489cb2434'	System	30 Aug 2020 10:58:17
User entered '96.9'	System	30 Aug 2020 10:58:17

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:54:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b7afec13-92a1-477e-859b-371489cb2434'	System	30 Aug 2020 10:58:17
User entered 'No (N)'	System	30 Aug 2020 10:58:17

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:54:55', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b7afec13-92a1-477e-859b-371489cb2434'	System	30 Aug 2020 10:58:17
User entered '30 Aug 2020 06:54'	System	30 Aug 2020 10:58:17

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 6'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:29', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '92ca33fb-2ca1-4497-87f5-32772501cbc4'	System	31 Aug 2020 04:33:49
User entered 'Yes (Y)'	System	31 Aug 2020 04:33:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '92ca33fb-2ca1-4497-87f5-32772501cbc4'	System	31 Aug 2020 04:33:49
User entered '97.0'	System	31 Aug 2020 04:33:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '92ca33fb-2ca1-4497-87f5-32772501cbc4'	System	31 Aug 2020 04:33:49
User entered 'No (N)'	System	31 Aug 2020 04:33:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '92ca33fb-2ca1-4497-87f5-32772501cbc4'	System	31 Aug 2020 04:33:49
User entered '31 Aug 2020 00:31'	System	31 Aug 2020 04:33:49

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 7'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:52:27', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'cb555dca-8751-454c-9303-80d96864c0b1'	System	31 Aug 2020 23:54:45
User entered 'Yes (Y)'	System	31 Aug 2020 23:54:45

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:52:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'cb555dca-8751-454c-9303-80d96864c0b1'	System	31 Aug 2020 23:54:45
User entered '97.0'	System	31 Aug 2020 23:54:45

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:52:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'cb555dca-8751-454c-9303-80d96864c0b1'	System	31 Aug 2020 23:54:45
User entered 'No (N)'	System	31 Aug 2020 23:54:45

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:52:44', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'cb555dca-8751-454c-9303-80d96864c0b1'	System	31 Aug 2020 23:54:45
User entered '31 Aug 2020 19:52'	System	31 Aug 2020 23:54:45

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:57:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '93cb7852-64c3-47e6-9504-3038018afd55'	System	25 Aug 2020 16:00:28
User entered 'None (1)'	System	25 Aug 2020 16:00:28

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '93cb7852-64c3-47e6-9504-3038018afd55'	System	25 Aug 2020 16:00:28
User entered 'No (N)'	System	25 Aug 2020 16:00:28

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '93cb7852-64c3-47e6-9504-3038018afd55'	System	25 Aug 2020 16:00:28
User entered 'No (N)'	System	25 Aug 2020 16:00:28

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:18', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '93cb7852-64c3-47e6-9504-3038018afd55'	System	25 Aug 2020 16:00:28
User entered 'None (1)'	System	25 Aug 2020 16:00:28

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:26', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '93cb7852-64c3-47e6-9504-3038018afd55'	System	25 Aug 2020 16:00:28
User entered '25 Aug 2020 11:58'	System	25 Aug 2020 16:00:28

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 11:46'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 14:16'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:30:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd92497cc-0807-4b2a-ac35-50751a2a0887'	System	26 Aug 2020 00:33:29
User entered 'None (1)'	System	26 Aug 2020 00:33:29

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd92497cc-0807-4b2a-ac35-50751a2a0887'	System	26 Aug 2020 00:33:29
User entered 'No (N)'	System	26 Aug 2020 00:33:29

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:12', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd92497cc-0807-4b2a-ac35-50751a2a0887'	System	26 Aug 2020 00:33:29
User entered 'No (N)'	System	26 Aug 2020 00:33:29

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:23', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd92497cc-0807-4b2a-ac35-50751a2a0887'	System	26 Aug 2020 00:33:29
User entered 'None (1)'	System	26 Aug 2020 00:33:29

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd92497cc-0807-4b2a-ac35-50751a2a0887'	System	26 Aug 2020 00:33:29
User entered '25 Aug 2020 20:31'	System	26 Aug 2020 00:33:29

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 15:11'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 2'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd380c393-f939-4a02-a1db-dd6262f18373'	System	27 Aug 2020 00:04:43
User entered 'None (1)'	System	27 Aug 2020 00:04:43

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:29', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd380c393-f939-4a02-a1db-dd6262f18373'	System	27 Aug 2020 00:04:43
User entered 'No (N)'	System	27 Aug 2020 00:04:43

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd380c393-f939-4a02-a1db-dd6262f18373'	System	27 Aug 2020 00:04:43
User entered 'No (N)'	System	27 Aug 2020 00:04:43

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd380c393-f939-4a02-a1db-dd6262f18373'	System	27 Aug 2020 00:04:43
User entered 'None (1)'	System	27 Aug 2020 00:04:43

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:41', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd380c393-f939-4a02-a1db-dd6262f18373'	System	27 Aug 2020 00:04:43
User entered '26 Aug 2020 20:02'	System	27 Aug 2020 00:04:43

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 3'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '33bf97c9-f1db-42b8-ba11-b4f4274eabd7'	System	27 Aug 2020 23:01:21
User entered 'None (1)'	System	27 Aug 2020 23:01:21

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '33bf97c9-f1db-42b8-ba11-b4f427eabd7'	System	27 Aug 2020 23:01:21
User entered 'No (N)'	System	27 Aug 2020 23:01:21

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:09', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '33bf97c9-f1db-42b8-ba11-b4f427eabd7'	System	27 Aug 2020 23:01:21
User entered 'No (N)'	System	27 Aug 2020 23:01:21

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '33bf97c9-f1db-42b8-ba11-b4f4274eabd7'	System	27 Aug 2020 23:01:21
User entered 'None (1)'	System	27 Aug 2020 23:01:21

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:21', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '33bf97c9-f1db-42b8-ba11-b4f4274eabd7'	System	27 Aug 2020 23:01:21
User entered '27 Aug 2020 18:59'	System	27 Aug 2020 23:01:21

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 4'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-28T19:46:31', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b383bad5-4af3-4a5d-b2cf-32541850c26b'	System	28 Aug 2020 23:48:46
User entered 'None (1)'	System	28 Aug 2020 23:48:46

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-28T19:46:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b383bad5-4af3-4a5d-b2cf-32541850c26b'	System	28 Aug 2020 23:48:46
User entered 'No (N)'	System	28 Aug 2020 23:48:46

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b383bad5-4af3-4a5d-b2cf-32541850c26b'	System	28 Aug 2020 23:48:46
User entered 'No (N)'	System	28 Aug 2020 23:48:46

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-28T19:46:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b383bad5-4af3-4a5d-b2cf-32541850c26b'	System	28 Aug 2020 23:48:46
User entered 'None (1)'	System	28 Aug 2020 23:48:46

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:45', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b383bad5-4af3-4a5d-b2cf-32541850c26b'	System	28 Aug 2020 23:48:46
User entered '28 Aug 2020 19:46'	System	28 Aug 2020 23:48:46

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 5'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-30T06:55:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '37af824f-aa59-4744-9041-712eb3be8c'	System	30 Aug 2020 10:57:19
User entered 'None (1)'	System	30 Aug 2020 10:57:19

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '37af824f-aa59-4744-9041-712ebed3be8c'	System	30 Aug 2020 10:57:19
User entered 'No (N)'	System	30 Aug 2020 10:57:19

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:09', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '37af824f-aa59-4744-9041-712ebed3be8c'	System	30 Aug 2020 10:57:19
User entered 'No (N)'	System	30 Aug 2020 10:57:19

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-30T06:55:12', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '37af824f-aa59-4744-9041-712eb3be8c'	System	30 Aug 2020 10:57:19
User entered 'None (1)'	System	30 Aug 2020 10:57:19

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '37af824f-aa59-4744-9041-712ebed3be8c'	System	30 Aug 2020 10:57:19
User entered '30 Aug 2020 06:55'	System	30 Aug 2020 10:57:19

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 6'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:54', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3fccaa59-76f4-4824-95b7-20ffc8a826e6'	System	31 Aug 2020 04:34:17
User entered 'None (1)'	System	31 Aug 2020 04:34:17

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:31:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3fccaa59-76f4-4824-95b7-20ffc8a826e6'	System	31 Aug 2020 04:34:17
User entered 'No (N)'	System	31 Aug 2020 04:34:17

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3fccaa59-76f4-4824-95b7-20ffc8a826e6'	System	31 Aug 2020 04:34:17
User entered 'No (N)'	System	31 Aug 2020 04:34:17

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3fccaa59-76f4-4824-95b7-20ffc8a826e6'	System	31 Aug 2020 04:34:17
User entered 'None (1)'	System	31 Aug 2020 04:34:17

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3fccaa59-76f4-4824-95b7-20ffc8a826e6'	System	31 Aug 2020 04:34:17
User entered '31 Aug 2020 00:32'	System	31 Aug 2020 04:34:17

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 7'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:52:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8d7df4e7-4ced-490e-b877-eb0d6c893099'	System	31 Aug 2020 23:55:06
User entered 'None (1)'	System	31 Aug 2020 23:55:06

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:52:53', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8d7df4e7-4ced-490e-b877-eb0d6c893099'	System	31 Aug 2020 23:55:06
User entered 'No (N)'	System	31 Aug 2020 23:55:06

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:52:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8d7df4e7-4ced-490e-b877-eb0d6c893099'	System	31 Aug 2020 23:55:06
User entered 'No (N)'	System	31 Aug 2020 23:55:06

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:52:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8d7df4e7-4ced-490e-b877-eb0d6c893099'	System	31 Aug 2020 23:55:06
User entered 'None (1)'	System	31 Aug 2020 23:55:06

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:53:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8d7df4e7-4ced-490e-b877-eb0d6c893099'	System	31 Aug 2020 23:55:06
User entered '31 Aug 2020 19:53'	System	31 Aug 2020 23:55:06

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:41', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:45', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:58:53', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'None (0)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:59:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered 'No (N)'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T11:59:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a939c657-3410-4a3a-a810-7ead53ce4302'	System	25 Aug 2020 16:01:19
User entered '25 Aug 2020 11:59'	System	25 Aug 2020 16:01:19

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 11:46'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 14:16'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:46', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:31:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'None (0)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:32:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered 'No (N)'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-25T20:32:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9007d190-a40b-4f58-b3ba-9264d05a0435'	System	26 Aug 2020 00:34:08
User entered '25 Aug 2020 20:32'	System	26 Aug 2020 00:34:08

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Aug 2020 15:11'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 2'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:51', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:54', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:02:57', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:03:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:03:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'None (0)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:03:10', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered 'No (N)'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-26T20:03:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29affb96-b6c8-4b80-89e2-c4419f96f9e0'	System	27 Aug 2020 00:05:23
User entered '26 Aug 2020 20:03'	System	27 Aug 2020 00:05:23

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 3'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:27', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:30', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'None (0)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:45', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered 'No (N)'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-27T18:59:49', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'b801154e-d30a-498b-8583-abf4b9cb0198'	System	27 Aug 2020 23:01:51
User entered '27 Aug 2020 18:59'	System	27 Aug 2020 23:01:51

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 4'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:54', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:46:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:47:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'None (0)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:47:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered 'No (N)'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-28T19:47:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '52a3710b-9dc2-42d4-884c-4fc501300442'	System	28 Aug 2020 23:49:11
User entered '28 Aug 2020 19:47'	System	28 Aug 2020 23:49:11

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 5'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:24', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-30T06:55:27', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:30', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'None (0)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered 'No (N)'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-30T06:55:51', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '66b6e5b9-c730-4c1b-af26-8ac2a1e5a25d'	System	30 Aug 2020 10:57:53
User entered '30 Aug 2020 06:55'	System	30 Aug 2020 10:57:53

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 6'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T00:32:22', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:24', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:26', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T00:32:29', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:35', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'None (0)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:38', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered 'No (N)'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T00:32:44', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '74caa00d-9fdc-43c5-9e49-78e9115f7a55'	System	31 Aug 2020 04:34:47
User entered '31 Aug 2020 00:32'	System	31 Aug 2020 04:34:47

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 7'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:53:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f'	System	31 Aug 2020 23:55:33
User entered 'None (0)'	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:53:14', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f' User entered 'None (0)'	System	31 Aug 2020 23:55:33
	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:53:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f' User entered 'None (0)'	System	31 Aug 2020 23:55:33
	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:53:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f' User entered 'None (0)'	System	31 Aug 2020 23:55:33
	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:53:22', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f' User entered 'None (0)'	System	31 Aug 2020 23:55:33
	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:53:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f' User entered 'None (0)'	System	31 Aug 2020 23:55:33
	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-08-31T19:53:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f'	System	31 Aug 2020 23:55:33
User entered 'No (N)'	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-08-31T19:53:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '30ce4b2f-4299-4083-9531-20e2c433705f'	System	31 Aug 2020 23:55:33
User entered '31 Aug 2020 19:53'	System	31 Aug 2020 23:55:33

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:31:26

US3742076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 23:21:01

US3742076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 23:21:01

US3742076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 23:21:01

US3742076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 23:21:01

US3742076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:15:37

US3742076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '1'	System	02 Sep 2020 15:15:37

US3742076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:35

US3742076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:35

US3742076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:35

US3742076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:35

US3742076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 23:10:01

US3742076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '1'	System	08 Sep 2020 23:10:01

US3742076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 22:33:42

US3742076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 22:33:42

US3742076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 22:33:42

US3742076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 22:33:42

US3742076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 22:33:52

US3742076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '1'	System	15 Sep 2020 22:33:52

US3742076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:24:44

US3742076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	22 Sep 2020 20:24:44

US3742076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	22 Sep 2020 20:24:44

US3742076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'VISIT2'	System	22 Sep 2020 20:24:44

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56
	(b) (4)	

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:11'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '22 Sep 2020 09:11'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '097.7' F	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '089'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'bpm'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '16'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'breaths/min'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '138'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '080'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '10:13'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '22 Sep 2020 10:13'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '097.1' F	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '068'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'bpm'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '14'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'breaths/min'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '145'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '074'	Sherry McCammon (b) (4)	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'mmHg'	System	22 Sep 2020 20:28:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:24:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	22 Sep 2020 20:24:56

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:42'	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '22 Sep 2020 09:42'	System	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'ONCE'	System	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 13:50:16

US3742076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:48

US3742076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:48

US3742076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:04'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:48

US3742076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '22 Sep 2020 09:04'	System	22 Sep 2020 20:25:48

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '22 Sep 2020'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '09:02'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '22 Sep 2020 09:02'	System	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	22 Sep 2020 20:25:32

US3742076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Sep 2020 20:25:52

US3742076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '1'	System	22 Sep 2020 20:25:52

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:13:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '312336f0-b0df-4d83-bc6d-ebe8a905ee6f'	System	22 Sep 2020 14:16:28
User entered 'Yes (Y)'	System	22 Sep 2020 14:16:28

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:13:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '312336f0-b0df-4d83-bc6d-ebe8a905ee6f' User entered '98.1'	System	22 Sep 2020 14:16:28

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:13:47', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '312336f0-b0df-4d83-bc6d-ebe8a905ee6f'	System	22 Sep 2020 14:16:28
User entered 'No (N)'	System	22 Sep 2020 14:16:28

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-22T10:13:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '312336f0-b0df-4d83-bc6d-ebe8a905ee6f' User entered '22 Sep 2020 10:13'	System	22 Sep 2020 14:16:28
	System	22 Sep 2020 14:16:28

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 10:02'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 12:32'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:18', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '77673019-4b38-4d55-b9b3-7255dd7e93c2'	System	22 Sep 2020 20:44:49
User entered 'Yes (Y)'	System	22 Sep 2020 20:44:49

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-22T16:42:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '77673019-4b38-4d55-b9b3-7255dd7e93c2'	System	22 Sep 2020 20:44:49
User entered '97.9'	System	22 Sep 2020 20:44:49

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '77673019-4b38-4d55-b9b3-7255dd7e93c2'	System	22 Sep 2020 20:44:49
User entered 'No (N)'	System	22 Sep 2020 20:44:49

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '77673019-4b38-4d55-b9b3-7255dd7e93c2'	System	22 Sep 2020 20:44:49
User entered '22 Sep 2020 16:42'	System	22 Sep 2020 20:44:49

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 13:27'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 2'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '5b6fc7eb-7b86-411f-a7e1-c0d5770da12c'	System	24 Sep 2020 01:22:35
User entered 'Yes (Y)'	System	24 Sep 2020 01:22:35

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:15', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '5b6fc7eb-7b86-411f-a7e1-c0d5770da12c'	System	24 Sep 2020 01:22:35
User entered '98.0'	System	24 Sep 2020 01:22:35

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '5b6fc7eb-7b86-411f-a7e1-c0d5770da12c'	System	24 Sep 2020 01:22:35
User entered 'No (N)'	System	24 Sep 2020 01:22:35

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:23', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '5b6fc7eb-7b86-411f-a7e1-c0d5770da12c'	System	24 Sep 2020 01:22:35
User entered '23 Sep 2020 21:20'	System	24 Sep 2020 01:22:35

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 3'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3d125084-3671-419e-8315-03beaa579624'	System	25 Sep 2020 13:39:47
User entered 'Yes (Y)'	System	25 Sep 2020 13:39:47

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3d125084-3671-419e-8315-03beaa579624' User entered '98.0'	System	25 Sep 2020 13:39:47
	System	25 Sep 2020 13:39:47

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:29', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3d125084-3671-419e-8315-03beaa579624'	System	25 Sep 2020 13:39:47
User entered 'No (N)'	System	25 Sep 2020 13:39:47

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:33', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3d125084-3671-419e-8315-03beaa579624'	System	25 Sep 2020 13:39:47
User entered '25 Sep 2020 09:37'	System	25 Sep 2020 13:39:47

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 4'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:51:57', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c56c4270-038a-4cba-9d09-7e33e8d7eea3'	System	25 Sep 2020 21:54:27
User entered 'Yes (Y)'	System	25 Sep 2020 21:54:27

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-25T17:52:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c56c4270-038a-4cba-9d09-7e33e8d7eea3'	System	25 Sep 2020 21:54:27
User entered '97.9'	System	25 Sep 2020 21:54:27

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:10', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c56c4270-038a-4cba-9d09-7e33e8d7eea3'	System	25 Sep 2020 21:54:27
User entered 'No (N)'	System	25 Sep 2020 21:54:27

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-25T17:52:15', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c56c4270-038a-4cba-9d09-7e33e8d7eea3'	System	25 Sep 2020 21:54:27
User entered '25 Sep 2020 17:52'	System	25 Sep 2020 21:54:27

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 5'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:13', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a61ad38a-0054-4311-97ab-be5b104b3f87'	System	27 Sep 2020 11:53:39
User entered 'Yes (Y)'	System	27 Sep 2020 11:53:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:21', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a61ad38a-0054-4311-97ab-be5b104b3f87' User entered '98.0'	System	27 Sep 2020 11:53:39
	System	27 Sep 2020 11:53:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:24', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a61ad38a-0054-4311-97ab-be5b104b3f87'	System	27 Sep 2020 11:53:39
User entered 'No (N)'	System	27 Sep 2020 11:53:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-27T07:51:27', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a61ad38a-0054-4311-97ab-be5b104b3f87'	System	27 Sep 2020 11:53:39
User entered '27 Sep 2020 07:51'	System	27 Sep 2020 11:53:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 6'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:09', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8252a30e-0499-470f-9a2b-a0778b708477'	System	27 Sep 2020 22:05:46
User entered 'Yes (Y)'	System	27 Sep 2020 22:05:46

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8252a30e-0499-470f-9a2b-a0778b708477'	System	27 Sep 2020 22:05:46
User entered '97.9'	System	27 Sep 2020 22:05:46

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:23', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8252a30e-0499-470f-9a2b-a0778b708477'	System	27 Sep 2020 22:05:46
User entered 'No (N)'	System	27 Sep 2020 22:05:46

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:27', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8252a30e-0499-470f-9a2b-a0778b708477'	System	27 Sep 2020 22:05:46
User entered '27 Sep 2020 18:03'	System	27 Sep 2020 22:05:46

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 7'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '76e31469-b3ff-4935-b73c-dace25420e27'	System	28 Sep 2020 22:46:39
User entered 'Yes (Y)'	System	28 Sep 2020 22:46:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:12', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '76e31469-b3ff-4935-b73c-dace25420e27'	System	28 Sep 2020 22:46:39
User entered '98.0'	System	28 Sep 2020 22:46:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '76e31469-b3ff-4935-b73c-dace25420e27'	System	28 Sep 2020 22:46:39
User entered 'No (N)'	System	28 Sep 2020 22:46:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:20', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '76e31469-b3ff-4935-b73c-dace25420e27'	System	28 Sep 2020 22:46:39
User entered '28 Sep 2020 18:44'	System	28 Sep 2020 22:46:39

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:13:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3a76e5c8-5e18-4928-8dc7-59820c904d76'	System	22 Sep 2020 14:16:51
User entered 'None (1)'	System	22 Sep 2020 14:16:51

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3a76e5c8-5e18-4928-8dc7-59820c904d76'	System	22 Sep 2020 14:16:51
User entered 'No (N)'	System	22 Sep 2020 14:16:51

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3a76e5c8-5e18-4928-8dc7-59820c904d76'	System	22 Sep 2020 14:16:51
User entered 'No (N)'	System	22 Sep 2020 14:16:51

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:12', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3a76e5c8-5e18-4928-8dc7-59820c904d76'	System	22 Sep 2020 14:16:51
User entered 'None (1)'	System	22 Sep 2020 14:16:51

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '3a76e5c8-5e18-4928-8dc7-59820c904d76'	System	22 Sep 2020 14:16:51
User entered '22 Sep 2020 10:14'	System	22 Sep 2020 14:16:51

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 10:02'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 12:32'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef05aace-fc2b-4f89-910a-3e8bfac4899d'	System	22 Sep 2020 20:45:13
User entered 'None (1)'	System	22 Sep 2020 20:45:13

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef05aace-fc2b-4f89-910a-3e8bfac4899d'	System	22 Sep 2020 20:45:13
User entered 'No (N)'	System	22 Sep 2020 20:45:13

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:55', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef05aace-fc2b-4f89-910a-3e8bfac4899d'	System	22 Sep 2020 20:45:13
User entered 'No (N)'	System	22 Sep 2020 20:45:13

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:42:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef05aace-fc2b-4f89-910a-3e8bfac4899d'	System	22 Sep 2020 20:45:13
User entered 'None (1)'	System	22 Sep 2020 20:45:13

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef05aace-fc2b-4f89-910a-3e8bfac4899d' User entered '22 Sep 2020 16:43'	System	22 Sep 2020 20:45:13
	System	22 Sep 2020 20:45:13

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 13:27'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 2'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:31', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c44bccc3-3b62-40f3-8304-bb04f6662367'	System	24 Sep 2020 01:23:04
User entered 'None (1)'	System	24 Sep 2020 01:23:04

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:41', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c44bccc3-3b62-40f3-8304-bb04f6662367'	System	24 Sep 2020 01:23:04
User entered 'No (N)'	System	24 Sep 2020 01:23:04

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:44', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c44bccc3-3b62-40f3-8304-bb04f6662367'	System	24 Sep 2020 01:23:04
User entered 'No (N)'	System	24 Sep 2020 01:23:04

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:46', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c44bccc3-3b62-40f3-8304-bb04f6662367'	System	24 Sep 2020 01:23:04
User entered 'None (1)'	System	24 Sep 2020 01:23:04

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'c44bccc3-3b62-40f3-8304-bb04f6662367'	System	24 Sep 2020 01:23:04
User entered '23 Sep 2020 21:20'	System	24 Sep 2020 01:23:04

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 3'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '01c04a8e-20be-456f-980f-3dffd8c5767a'	System	25 Sep 2020 13:40:03
User entered 'None (1)'	System	25 Sep 2020 13:40:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '01c04a8e-20be-456f-980f-3dffd8c5767a'	System	25 Sep 2020 13:40:03
User entered 'No (N)'	System	25 Sep 2020 13:40:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:45', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '01c04a8e-20be-456f-980f-3dffd8c5767a'	System	25 Sep 2020 13:40:03
User entered 'No (N)'	System	25 Sep 2020 13:40:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-25T09:37:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '01c04a8e-20be-456f-980f-3dffd8c5767a'	System	25 Sep 2020 13:40:03
User entered 'None (1)'	System	25 Sep 2020 13:40:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:51', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '01c04a8e-20be-456f-980f-3dffd8c5767a'	System	25 Sep 2020 13:40:03
User entered '25 Sep 2020 09:37'	System	25 Sep 2020 13:40:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 4'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:20', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '794dc963-ba78-4038-a5a3-f26389aa9514'	System	25 Sep 2020 21:54:45
User entered 'None (1)'	System	25 Sep 2020 21:54:45

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:22', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '794dc963-ba78-4038-a5a3-f26389aa9514'	System	25 Sep 2020 21:54:45
User entered 'No (N)'	System	25 Sep 2020 21:54:45

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '794dc963-ba78-4038-a5a3-f26389aa9514'	System	25 Sep 2020 21:54:45
User entered 'No (N)'	System	25 Sep 2020 21:54:45

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '794dc963-ba78-4038-a5a3-f26389aa9514'	System	25 Sep 2020 21:54:45
User entered 'None (1)'	System	25 Sep 2020 21:54:45

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '794dc963-ba78-4038-a5a3-f26389aa9514'	System	25 Sep 2020 21:54:45
User entered '25 Sep 2020 17:52'	System	25 Sep 2020 21:54:45

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 5'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8f1f6a1-01c3-4a06-b285-d24513d61bdf'	System	27 Sep 2020 11:53:54
User entered 'None (1)'	System	27 Sep 2020 11:53:54

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8f1f6a1-01c3-4a06-b285-d24513d61bdf'	System	27 Sep 2020 11:53:54
User entered 'No (N)'	System	27 Sep 2020 11:53:54

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8f1f6a1-01c3-4a06-b285-d24513d61bdf'	System	27 Sep 2020 11:53:54
User entered 'No (N)'	System	27 Sep 2020 11:53:54

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8f1f6a1-01c3-4a06-b285-d24513d61bdf'	System	27 Sep 2020 11:53:54
User entered 'None (1)'	System	27 Sep 2020 11:53:54

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8f1f6a1-01c3-4a06-b285-d24513d61bdf'	System	27 Sep 2020 11:53:54
User entered '27 Sep 2020 07:51'	System	27 Sep 2020 11:53:54

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 6'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '59876820-a315-4408-bd59-fdddb155cfcc'	System	27 Sep 2020 22:06:03
User entered 'None (1)'	System	27 Sep 2020 22:06:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:35', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '59876820-a315-4408-bd59-fdddb155cfcc'	System	27 Sep 2020 22:06:03
User entered 'No (N)'	System	27 Sep 2020 22:06:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '59876820-a315-4408-bd59-fdddb155cfcc'	System	27 Sep 2020 22:06:03
User entered 'No (N)'	System	27 Sep 2020 22:06:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '59876820-a315-4408-bd59-fdddb155cfcc'	System	27 Sep 2020 22:06:03
User entered 'None (1)'	System	27 Sep 2020 22:06:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '59876820-a315-4408-bd59-fdddb155cfcc'	System	27 Sep 2020 22:06:03
User entered '27 Sep 2020 18:03'	System	27 Sep 2020 22:06:03

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 7'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '1e8e2c7c-7ed7-4f87-9e3a-fc763ecf03dc'	System	28 Sep 2020 22:47:01
User entered 'None (1)'	System	28 Sep 2020 22:47:01

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:44:29', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '1e8e2c7c-7ed7-4f87-9e3a-fc763ecf03dc'	System	28 Sep 2020 22:47:01
User entered 'No (N)'	System	28 Sep 2020 22:47:01

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '1e8e2c7c-7ed7-4f87-9e3a-fc763ecf03dc'	System	28 Sep 2020 22:47:01
User entered 'No (N)'	System	28 Sep 2020 22:47:01

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:44:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '1e8e2c7c-7ed7-4f87-9e3a-fc763ecf03dc'	System	28 Sep 2020 22:47:01
User entered 'None (1)'	System	28 Sep 2020 22:47:01

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:44:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '1e8e2c7c-7ed7-4f87-9e3a-fc763ecf03dc'	System	28 Sep 2020 22:47:01
User entered '28 Sep 2020 18:44'	System	28 Sep 2020 22:47:01

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:22', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'None (0)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:24', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'None (0)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'None (0)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:30', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'None (0)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'None (0)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:36', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24' User entered 'None (0)'	System	22 Sep 2020 14:17:15
	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24'	System	22 Sep 2020 14:17:15
User entered 'No (N)'	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T10:14:44', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9f77c595-4951-4220-b504-7e53d5fd9b24' User entered '22 Sep 2020 10:14'	System	22 Sep 2020 14:17:15
	System	22 Sep 2020 14:17:15

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 10:02'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 12:32'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:09', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:13', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:15', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:18', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'None (0)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:21', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered 'No (N)'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-22T16:43:24', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8a04d3b8-0a24-4204-b0b8-7f3c12f0853b'	System	22 Sep 2020 20:45:36
User entered '22 Sep 2020 16:43'	System	22 Sep 2020 20:45:36

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '22 Sep 2020 13:27'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 2'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:55', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:20:57', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'None (0)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered 'No (N)'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-23T21:21:13', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a2f8c033-7b6b-4a31-9e94-7259ef81ccd2'	System	24 Sep 2020 01:23:24
User entered '23 Sep 2020 21:21'	System	24 Sep 2020 01:23:24

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 3'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:37:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:09', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:12', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'None (0)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:15', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered 'No (N)'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T09:38:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '95610a8d-ad3b-4dfa-92ed-22452a67b78c'	System	25 Sep 2020 13:40:32
User entered '25 Sep 2020 09:38'	System	25 Sep 2020 13:40:32

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 4'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-25T17:52:41', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:44', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:46', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:49', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'None (0)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-25T17:52:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered 'No (N)'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-25T17:52:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '2dc178b5-4be8-4600-8373-7e0afa65d102'	System	25 Sep 2020 21:55:13
User entered '25 Sep 2020 17:52'	System	25 Sep 2020 21:55:13

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 5'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:46', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d' User entered 'None (0)'	System	27 Sep 2020 11:54:16
	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'None (0)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:50', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'None (0)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'None (0)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:54', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'None (0)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'None (0)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:51:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered 'No (N)'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T07:52:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '418dba97-492a-4366-8f12-47ec473d353d'	System	27 Sep 2020 11:54:16
User entered '27 Sep 2020 07:52'	System	27 Sep 2020 11:54:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 6'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-27T18:03:49', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:51', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:53', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:56', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:03:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'None (0)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-27T18:04:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered 'No (N)'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-27T18:04:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4cc94be9-7e98-4f27-9003-1038adf29174'	System	27 Sep 2020 22:06:28
User entered '27 Sep 2020 18:04'	System	27 Sep 2020 22:06:28

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	22 Sep 2020 13:50:16
User entered 'Day 7'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:44:55', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:44:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:45:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:45:03', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:45:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-09-28T18:45:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'None (0)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:45:15', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered 'No (N)'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-09-28T18:45:18', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f8060786-7f11-43e2-9e64-3fd8b36fe132'	System	28 Sep 2020 22:47:37
User entered '28 Sep 2020 18:45'	System	28 Sep 2020 22:47:37

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:50:16

US3742076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:50:16

US3742076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 13:46:56

US3742076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '29 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 13:46:56

US3742076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	30 Sep 2020 13:46:56

US3742076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 13:46:56

US3742076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 13:46:47

US3742076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'I'	System	30 Sep 2020 13:46:47

US3742076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 20:07:28

US3742076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '6 Oct 2020'	Hassan Haji (b) (4)	06 Oct 2020 20:07:28

US3742076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	06 Oct 2020 20:07:28

US3742076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	06 Oct 2020 20:07:28

US3742076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Oct 2020 20:07:32

US3742076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'I'	System	06 Oct 2020 20:07:32

US3742076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 20:24:58

US3742076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '13 Oct 2020'	Hassan Haji (b) (4)	13 Oct 2020 20:24:58

US3742076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 20:24:58

US3742076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 20:24:58

US3742076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 20:25:33

US3742076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'I'	System	13 Oct 2020 20:25:33

US3742076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:09:53

US3742076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '20 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 14:09:53

US3742076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[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 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Clinic (Clinic)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:09:53

US3742076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'VISIT3'	System	20 Oct 2020 14:09:53

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered empty.	System	20 Oct 2020 14:10:04

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00

US3742076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00

US3742076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:32

US3742076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '20 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:32

US3742076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:46

US3742076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '20 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:46

US3742076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered '08:05'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 14:10:46

US3742076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered '20 Oct 2020 08:05'	System	20 Oct 2020 14:10:46

US3742076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:07:53
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 14:10:51

US3742076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'I'	System	20 Oct 2020 14:10:51

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 64'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:17
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 71'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbee3c99f2)', Time: '2020-11-02T15:55:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf3324c8-864f-45aa-8a2f-2bc6f2e02229'	System	02 Nov 2020 20:58:43
User entered 'No (N)'	System	02 Nov 2020 20:58:43

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbee3c99f2)', Time: '2020-11-02T15:56:02', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf3324c8-864f-45aa-8a2f-2bc6f2e02229'	System	02 Nov 2020 20:58:43
User entered 'No (N)'	System	02 Nov 2020 20:58:43

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-11-02T15:56:10', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf3324c8-864f-45aa-8a2f-2bc6f2e02229'	System	02 Nov 2020 20:58:43
User entered '02 Nov 2020 15:56:10'	System	02 Nov 2020 20:58:43

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered 'Day 78'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-11-08T09:50:04', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '47e17c3f-00bb-4dd5-bd21-c68bf5d37537'	System	08 Nov 2020 14:52:53
User entered 'No (N)'	System	08 Nov 2020 14:52:53

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-11-08T09:50:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '47e17c3f-00bb-4dd5-bd21-c68bf5d37537'	System	08 Nov 2020 14:52:53
User entered 'No (N)'	System	08 Nov 2020 14:52:53

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2020-11-08T09:50:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '47e17c3f-00bb-4dd5-bd21-c68bf5d37537'	System	08 Nov 2020 14:52:53
User entered '08 Nov 2020 09:50:17'	System	08 Nov 2020 14:52:53

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 15:31:26

US3742076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:38:15
Data entry locked.	System	25 Aug 2020 15:31:26
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 15:31:26

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2020-11-23T17:29:42', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f6e851b8-f2a6-40eb-ade3-e72d3cbe1511'	System	23 Nov 2020 22:32:37
User entered 'No (N)'	System	23 Nov 2020 22:32:37

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2020-11-23T17:29:45', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f6e851b8-f2a6-40eb-ade3-e72d3cbe1511'	System	23 Nov 2020 22:32:37
User entered 'No (N)'	System	23 Nov 2020 22:32:37

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-11-23T17:29:52', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'f6e851b8-f2a6-40eb-ade3-e72d3cbe1511'	System	23 Nov 2020 22:32:37
User entered '23 Nov 2020 17:29:52'	System	23 Nov 2020 22:32:37

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2020-11-30T14:14:20', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '08182f73-3abf-4abd-83a5-b86e00a52117'	System	30 Nov 2020 19:17:19
User entered 'No (N)'	System	30 Nov 2020 19:17:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2020-11-30T14:14:25', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '08182f73-3abf-4abd-83a5-b86e00a52117'	System	30 Nov 2020 19:17:19
User entered 'No (N)'	System	30 Nov 2020 19:17:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-11-30T14:14:31', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '08182f73-3abf-4abd-83a5-b86e00a52117'	System	30 Nov 2020 19:17:19
User entered '30 Nov 2020 14:14:31'	System	30 Nov 2020 19:17:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbee3c99f2)', Time: '2020-12-05T15:22:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ee8048ca-ae90-4fb2-916c-fe3cb2bb2e3f'	System	05 Dec 2020 20:24:59
User entered 'No (N)'	System	05 Dec 2020 20:24:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2020-12-05T15:22:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ee8048ca-ae90-4fb2-916c-fe3cb2bb2e3f'	System	05 Dec 2020 20:24:59
User entered 'No (N)'	System	05 Dec 2020 20:24:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-05T15:22:11', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ee8048ca-ae90-4fb2-916c-fe3cb2bb2e3f'	System	05 Dec 2020 20:24:59
User entered '05 Dec 2020 15:22:11'	System	05 Dec 2020 20:24:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2020-12-14T07:14:31', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '53fac0d9-a846-4f2a-b509-5bc7148ad050'	System	14 Dec 2020 12:17:39
User entered 'No (N)'	System	14 Dec 2020 12:17:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdbee3c99f2)', Time: '2020-12-14T07:14:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '53fac0d9-a846-4f2a-b509-5bc7148ad050'	System	14 Dec 2020 12:17:39
User entered 'No (N)'	System	14 Dec 2020 12:17:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-14T07:14:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '53fac0d9-a846-4f2a-b509-5bc7148ad050'	System	14 Dec 2020 12:17:39
User entered '14 Dec 2020 07:14:43'	System	14 Dec 2020 12:17:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2020-12-21T06:49:47', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered 'Yes (Y)'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2020-12-21T06:49:53', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered 'No (N)'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-21T06:49:59', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered 'No (N)'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-21T06:50:07', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered 'Yes (Y)'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-21T06:50:16', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-21T06:50:26', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '29b381d7-e8e7-4ec9-ace2-aac5c1f692b7'	System	21 Dec 2020 11:53:29
User entered '21 Dec 2020 06:50:26'	System	21 Dec 2020 11:53:29

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2020-12-25T15:49:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '10505a8b-0709-4299-aa83-29fce0fd9bc6'	System	25 Dec 2020 20:52:39
User entered 'No (N)'	System	25 Dec 2020 20:52:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2020-12-25T15:49:32', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '10505a8b-0709-4299-aa83-29fce0fd9bc6'	System	25 Dec 2020 20:52:39
User entered 'No (N)'	System	25 Dec 2020 20:52:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2020-12-25T15:49:41', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '10505a8b-0709-4299-aa83-29fce0fd9bc6'	System	25 Dec 2020 20:52:39
User entered '25 Dec 2020 15:49:41'	System	25 Dec 2020 20:52:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-01-02T09:41:08', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '6c0c6d65-44b8-41c0-8c64-0890a32d77ae'	System	02 Jan 2021 14:44:21
User entered 'No (N)'	System	02 Jan 2021 14:44:21

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2021-01-02T09:41:13', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '6c0c6d65-44b8-41c0-8c64-0890a32d77ae'	System	02 Jan 2021 14:44:21
User entered 'No (N)'	System	02 Jan 2021 14:44:21

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-02T09:41:18', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '6c0c6d65-44b8-41c0-8c64-0890a32d77ae'	System	02 Jan 2021 14:44:21
User entered '02 Jan 2021 09:41:18'	System	02 Jan 2021 14:44:21

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2021-01-08T15:41:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf323e55-2da4-4022-ac4f-4d169ab64607'	System	08 Jan 2021 20:44:59
User entered 'No (N)'	System	08 Jan 2021 20:44:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-01-08T15:41:48', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf323e55-2da4-4022-ac4f-4d169ab64607'	System	08 Jan 2021 20:44:59
User entered 'No (N)'	System	08 Jan 2021 20:44:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-08T15:41:53', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'bf323e55-2da4-4022-ac4f-4d169ab64607'	System	08 Jan 2021 20:44:59
User entered '08 Jan 2021 15:41:53'	System	08 Jan 2021 20:44:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-01-17T09:30:34', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered 'Yes (Y)'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-01-17T09:30:40', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered 'No (N)'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-17T09:30:47', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered 'No (N)'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-17T09:31:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered 'Yes (Y)'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-01-17T09:31:10', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-17T09:31:28', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '99aa4991-d845-4c24-8cc6-59909cd9cea8'	System	17 Jan 2021 14:34:42
User entered '17 Jan 2021 09:31:28'	System	17 Jan 2021 14:34:42

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-01-22T12:13:37', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4d217e10-546c-4c09-be6d-b37c9daba866'	System	22 Jan 2021 17:16:59
User entered 'No (N)'	System	22 Jan 2021 17:16:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2021-01-22T12:13:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4d217e10-546c-4c09-be6d-b37c9daba866'	System	22 Jan 2021 17:16:59
User entered 'No (N)'	System	22 Jan 2021 17:16:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-22T12:13:47', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '4d217e10-546c-4c09-be6d-b37c9daba866'	System	22 Jan 2021 17:16:59
User entered '22 Jan 2021 12:13:47'	System	22 Jan 2021 17:16:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2021-01-28T07:52:06', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '7940dcb7-fab4-436e-be27-5b42323153d6'	System	28 Jan 2021 12:55:32
User entered 'No (N)'	System	28 Jan 2021 12:55:32

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-01-28T07:52:14', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '7940dcb7-fab4-436e-be27-5b42323153d6'	System	28 Jan 2021 12:55:32
User entered 'No (N)'	System	28 Jan 2021 12:55:32

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-01-28T07:52:19', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '7940dcb7-fab4-436e-be27-5b42323153d6'	System	28 Jan 2021 12:55:32
User entered '28 Jan 2021 07:52:19'	System	28 Jan 2021 12:55:32

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-02-08T10:24:58', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '626fda90-932b-4b89-a557-09da0a84be65'	System	08 Feb 2021 15:28:19
User entered 'No (N)'	System	08 Feb 2021 15:28:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-02-08T10:25:01', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '626fda90-932b-4b89-a557-09da0a84be65'	System	08 Feb 2021 15:28:19
User entered 'No (N)'	System	08 Feb 2021 15:28:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-02-08T10:25:05', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '626fda90-932b-4b89-a557-09da0a84be65'	System	08 Feb 2021 15:28:19
User entered '08 Feb 2021 10:25:05'	System	08 Feb 2021 15:28:19

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-02-11T09:49:14', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a8d8e69a-161f-4f81-85c5-344d6f62f107'	System	11 Feb 2021 14:52:41
User entered 'No (N)'	System	11 Feb 2021 14:52:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-02-11T09:49:17', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a8d8e69a-161f-4f81-85c5-344d6f62f107'	System	11 Feb 2021 14:52:41
User entered 'No (N)'	System	11 Feb 2021 14:52:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-02-11T09:49:21', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a8d8e69a-161f-4f81-85c5-344d6f62f107'	System	11 Feb 2021 14:52:41
User entered '11 Feb 2021 09:49:21'	System	11 Feb 2021 14:52:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2021-02-18T10:24:39', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ba0ad719-d5a3-4202-8fb7-3fd6d348647e'	System	18 Feb 2021 15:28:07
User entered 'No (N)'	System	18 Feb 2021 15:28:07

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-02-18T10:24:43', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ba0ad719-d5a3-4202-8fb7-3fd6d348647e'	System	18 Feb 2021 15:28:07
User entered 'No (N)'	System	18 Feb 2021 15:28:07

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-02-18T10:24:46', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ba0ad719-d5a3-4202-8fb7-3fd6d348647e'	System	18 Feb 2021 15:28:07
User entered '18 Feb 2021 10:24:46'	System	18 Feb 2021 15:28:07

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-02-25T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a277da0c-288b-4bac-9e90-3eee6828c89d' User entered 'No (N)'	System	25 Feb 2021 05:06:39
	System	25 Feb 2021 05:06:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-02-25T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a277da0c-288b-4bac-9e90-3eee6828c89d'	System	25 Feb 2021 05:06:39
User entered 'No (N)'	System	25 Feb 2021 05:06:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-02-25T00:02:37-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'a277da0c-288b-4bac-9e90-3eee6828c89d' User entered '25 Feb 2021 00:02:37'	System	25 Feb 2021 05:06:39
	System	25 Feb 2021 05:06:39

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-03-04T08:38:07-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef7b3b01-aa40-4a77-8e59-a7238583a591'	System	04 Mar 2021 13:41:41
User entered 'No (N)'	System	04 Mar 2021 13:41:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-03-04T08:38:10-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef7b3b01-aa40-4a77-8e59-a7238583a591'	System	04 Mar 2021 13:41:41
User entered 'No (N)'	System	04 Mar 2021 13:41:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-03-04T08:38:13-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef7b3b01-aa40-4a77-8e59-a7238583a591'	System	04 Mar 2021 13:41:41
User entered '04 Mar 2021 08:38:13'	System	04 Mar 2021 13:41:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-03-11T11:40:13-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '85256ca4-3ad2-4904-b70d-1f9c0c1722b0'	System	11 Mar 2021 16:43:52
User entered 'No (N)'	System	11 Mar 2021 16:43:52

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-03-11T11:40:16-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '85256ca4-3ad2-4904-b70d-1f9c0c1722b0'	System	11 Mar 2021 16:43:52
User entered 'No (N)'	System	11 Mar 2021 16:43:52

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-03-11T11:40:20-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '85256ca4-3ad2-4904-b70d-1f9c0c1722b0'	System	11 Mar 2021 16:43:52
User entered '11 Mar 2021 11:40:20'	System	11 Mar 2021 16:43:52

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-03-18T09:16:34-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'e52a1964-95d9-4d4e-83a9-cb578d87431f'	System	18 Mar 2021 13:20:11
User entered 'No (N)'	System	18 Mar 2021 13:20:11

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-03-18T09:16:38-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'e52a1964-95d9-4d4e-83a9-cb578d87431f'	System	18 Mar 2021 13:20:11
User entered 'No (N)'	System	18 Mar 2021 13:20:11

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-03-18T09:16:42-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'e52a1964-95d9-4d4e-83a9-cb578d87431f' User entered '18 Mar 2021 09:16:42'	System	18 Mar 2021 13:20:11
	System	18 Mar 2021 13:20:11

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2021-03-25T10:45:14-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef2498b6-ba88-4c30-9e29-97d19efac096'	System	25 Mar 2021 14:48:59
User entered 'No (N)'	System	25 Mar 2021 14:48:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-03-25T10:45:16-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef2498b6-ba88-4c30-9e29-97d19efac096'	System	25 Mar 2021 14:48:59
User entered 'No (N)'	System	25 Mar 2021 14:48:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-03-25T10:45:20-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ef2498b6-ba88-4c30-9e29-97d19efac096'	System	25 Mar 2021 14:48:59
User entered '25 Mar 2021 10:45:20'	System	25 Mar 2021 14:48:59

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-04-01T08:30:12-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ea55991a-24ad-49e5-a249-7bb194cc3c4a' User entered 'No (N)'	System	01 Apr 2021 12:34:00
	System	01 Apr 2021 12:34:00

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-04-01T08:30:16-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ea55991a-24ad-49e5-a249-7bb194cc3c4a'	System	01 Apr 2021 12:34:00
User entered 'No (N)'	System	01 Apr 2021 12:34:00

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-04-01T08:30:20-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'ea55991a-24ad-49e5-a249-7bb194cc3c4a' User entered '01 Apr 2021 08:30:20'	System	01 Apr 2021 12:34:00
	System	01 Apr 2021 12:34:00

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-04-08T09:25:40-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '268d9b13-cb6a-4121-b857-a6fd50555c85'	System	08 Apr 2021 13:29:35
User entered 'No (N)'	System	08 Apr 2021 13:29:35

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbec3c99f2)', Time: '2021-04-08T09:25:43-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '268d9b13-cb6a-4121-b857-a6fd50555c85'	System	08 Apr 2021 13:29:35
User entered 'No (N)'	System	08 Apr 2021 13:29:35

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-04-08T09:25:46-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '268d9b13-cb6a-4121-b857-a6fd50555c85'	System	08 Apr 2021 13:29:35
User entered '08 Apr 2021 09:25:46'	System	08 Apr 2021 13:29:35

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdbec3c99f2)', Time: '2021-04-16T14:04:45-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9c2cb7ec-adb7-4bbf-84ce-a72bdd2b0fb1' User entered 'No (N)'	System	16 Apr 2021 18:08:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdbee3c99f2)', Time: '2021-04-16T14:04:48-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9c2cb7ec-adb7-4bbf-84ce-a72bdd2b0fb1'	System	16 Apr 2021 18:08:41
User entered 'No (N)'	System	16 Apr 2021 18:08:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-04-16T14:04:51-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '9c2cb7ec-adb7-4bbf-84ce-a72bdd2b0fb1' User entered '16 Apr 2021 14:04:51'	System	16 Apr 2021 18:08:41
	System	16 Apr 2021 18:08:41

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-04-26T15:13:49-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd609d397-dcf2-4a70-ad41-59813a36a89b'	System	26 Apr 2021 19:17:45
User entered 'No (N)'	System	26 Apr 2021 19:17:45

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2021-04-26T15:13:52-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd609d397-dcf2-4a70-ad41-59813a36a89b'	System	26 Apr 2021 19:17:45
User entered 'No (N)'	System	26 Apr 2021 19:17:45

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdb3c99f2)', Time: '2021-04-26T15:13:56-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: 'd609d397-dcf2-4a70-ad41-59813a36a89b'	System	26 Apr 2021 19:17:45
User entered '26 Apr 2021 15:13:56'	System	26 Apr 2021 19:17:45

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[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 (54f1acdb3c99f2)', Time: '2021-04-29T10:42:42-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '0c119938-562d-4196-8561-1fa1d1799b61'	System	29 Apr 2021 15:13:02
User entered 'No (N)'	System	29 Apr 2021 15:13:02

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

Have you been exposed to someone with 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 (54f1acdb3c99f2)', Time: '2021-04-29T10:42:44-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '0c119938-562d-4196-8561-1fa1d1799b61'	System	29 Apr 2021 15:13:02
User entered 'No (N)'	System	29 Apr 2021 15:13:02

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-04-29T10:42:46-04:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '0c119938-562d-4196-8561-1fa1d1799b61' User entered '29 Apr 2021 10:42:46'	System	29 Apr 2021 15:13:02
	System	29 Apr 2021 15:13:02

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:15:17

US3742076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:17
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:15:17

US3742076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:30:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-03-03T15:33:17-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8971ecda-6406-4e2c-a316-389bb45db750'	System	03 Mar 2021 20:36:53
User entered 'No (N)'	System	03 Mar 2021 20:36:53

US3742076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:30:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:38:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (54f1acdbec3c99f2)', Time: '2021-03-03T15:33:25-05:00', User OID: 'PatientReportedOutcome (US3742076)', ODM File OID: '8971ecda-6406-4e2c-a316-389bb45db750' User entered '03 Mar 2021 15:33:25'	System	03 Mar 2021 20:36:53
	System	03 Mar 2021 20:36:53

US3742076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 20:52:32

US3742076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '17 Nov 2020'	Hassan Haji (b) (4)	17 Nov 2020 20:52:32

US3742076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	17 Nov 2020 20:52:32

US3742076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Hassan Haji (b) (4)	17 Nov 2020 20:52:32

US3742076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Nov 2020 20:52:37

US3742076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:49:00
User entered 'I'	System	17 Nov 2020 20:52:37

US3742076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 21:05:45

US3742076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:05:45

US3742076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Dec 2020 21:05:45

US3742076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:05:45

US3742076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 21:05:59

US3742076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User entered 'I'	System	21 Dec 2020 21:05:59

US3742076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 15:52:37
	(b) (4)	

US3742076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '21 Jan 2021'	Sherry McCammon (b) (4)	25 Jan 2021 15:52:37
	(b) (4)	

US3742076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Jan 2021 15:52:37
	(b) (4)	

US3742076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 15:52:37
	(b) (4)	

US3742076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 15:52:42
	(b) (4)	

US3742076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User entered 'I'	System	25 Jan 2021 15:52:42

US3742076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Feb 2021 13:18:41
	(b) (4)	

US3742076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '19 Feb 2021'	Sherry McCammon (b) (4)	23 Feb 2021 13:18:41
	(b) (4)	

US3742076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Feb 2021 13:18:41
	(b) (4)	

US3742076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 13:18:41
	(b) (4)	

US3742076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Feb 2021 13:18:49
	(b) (4)	

US3742076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:29:40
User entered 'I'	System	23 Feb 2021 13:18:49

US3742076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered 'VISIT4'	System	01 Apr 2021 15:22:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered empty.	System	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered empty.	System	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered empty.	System	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered empty.	System	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered empty.	System	01 Apr 2021 15:22:54

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53

US3742076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53

US3742076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:20

US3742076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:33

US3742076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:33

US3742076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '09:04'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:33

US3742076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered '01 Apr 2021 09:04'	System	01 Apr 2021 15:23:33

US3742076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:23:41

US3742076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:53
User entered 'I'	System	01 Apr 2021 15:23:41

US3742076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:53:28
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 14:52:24

US3742076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:53:28
	(b) (4)	
User entered '22 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 14:52:24

US3742076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:53:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:52:24

US3742076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:53:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 14:52:24

US3742076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:53:28
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 14:52:33

US3742076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 14:52:33

US3742076

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:24:34

US3742076

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:24:34

US3742076

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Clinic (Clinic)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:24:34

US3742076

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 20:24:34

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:11

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
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 17:28:11

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Placebo (Placebo)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Placebo (Placebo)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Placebo (Placebo)'	Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '1'	System	04 Feb 2021 20:28:50

US3742076

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'I'	System	04 Feb 2021 20:28:50

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered empty.	System	04 Feb 2021 20:36:38
DataPoint set to visible.	System	04 Feb 2021 20:28:50

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered empty.	System	04 Feb 2021 20:36:38
DataPoint set to visible.	System	04 Feb 2021 20:28:50

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	04 Feb 2021 20:36:38
	(b) (4)	

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '09:45'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Feb 2021 09:45'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '098.1' F	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Oral (Oral)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '068'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'bpm'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '16'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'breaths/min'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '124'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '062'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered empty.	System	04 Feb 2021 20:36:38
DataPoint set to visible.	System	04 Feb 2021 20:28:50

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '10:28'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Feb 2021 10:28'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '099.0' F	Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Other (Other)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'temporal'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '065'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'bpm'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '14'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'breaths/min'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '113'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '065'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:38

US3742076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Feb 2021 20:36:38

US3742076

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:29:14

US3742076

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:29:14

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mRNA-1273'	System	04 Feb 2021 20:33:46
DataPoint set to visible.	System	04 Feb 2021 20:28:50

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '09:58'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Feb 2021 09:58'	System	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Left Arm (LEFT ARM)'	Sherry McCammon (b) (4)	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'ONCE'	System	04 Feb 2021 20:33:46

US3742076

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

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 20:33:46

US3742076

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:26

US3742076

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:26

US3742076

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '09:20'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:26

US3742076

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Feb 2021 09:20'	System	04 Feb 2021 20:25:26

US3742076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:07

US3742076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '4 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:07

US3742076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '09:21'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:25:07

US3742076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Feb 2021 09:21'	System	04 Feb 2021 20:25:07

US3742076

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

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 20:36:59

US3742076

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

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'I'	System	04 Feb 2021 20:36:59

US3742076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:03
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:15:55

US3742076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:03
User entered '11 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:15:55

US3742076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:15:55

US3742076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:15:55

US3742076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:00:03
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:16:03

US3742076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'I'	System	15 Feb 2021 16:16:03

US3742076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '1'	System	15 Feb 2021 16:16:03
DataPoint set to visible.	System	15 Feb 2021 16:16:03

US3742076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:44:42

US3742076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 19:44:42

US3742076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	04 Mar 2021 19:44:42

US3742076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'OLD29'	System	04 Mar 2021 19:44:42

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10
	(b) (4)	

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '10:04'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Mar 2021 10:04'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '097.8' F	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '065'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'bpm'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '16'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'breaths/min'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '145'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '075'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '10:46'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Mar 2021 10:46'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '097.4' F	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Other (Other)'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'temporal'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '067'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'bpm'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '14'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'breaths/min'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '123'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '075'	Sherry McCammon (b) (4)	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mmHg'	System	04 Mar 2021 19:49:10

US3742076

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:45:34

US3742076

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 19:45:34

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'mRNA-1273'	System	04 Mar 2021 19:46:12
DataPoint set to visible.	System	15 Feb 2021 16:16:03

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '10:15'	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered '4 Mar 2021 10:15'	System	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Left Arm (LEFT ARM)'	Sherry McCammon (b) (4)	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'ONCE'	System	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 19:46:12

US3742076

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 19:45:01

US3742076

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'I'	System	04 Mar 2021 19:45:01

US3742076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:16:16

US3742076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:16:16

US3742076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:16:16

US3742076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:16:16

US3742076

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:16:23

US3742076

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:42
User entered 'I'	System	15 Mar 2021 19:16:23

US3742076

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:14

US3742076

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:14

US3742076

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:14

US3742076

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:43

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 15:19:14

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:19:43

US3742076

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 15:20:02

US3742076

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:20:02

US3742076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:20:37

US3742076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:20:37

US3742076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '09:04'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:20:37

US3742076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:43

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

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:04'	System	01 Apr 2021 15:20:37

US3742076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:30:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:20
User closed query 'Per DM CLR: Per Day 117 on Safety Follow-up Diary Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:04:16
Query 'Per DM CLR: Per Day 117 on Safety Follow-up Diary Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'No AE required as it was a routine pre-operative appointment.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:35:44
User opened query 'Per DM CLR: Per Day 117 on Safety Follow-up Diary Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:26:34
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:10:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Jan 2021 20:29:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered	(b) (4)	20 Jan 2021 19:25:06
'USA-US127-2021-mRNA-1273-P301000007'	System	20 Jan 2021 19:25:06
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 19:25:06

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:54:41
User closed query 'For coding purposes, TOTAL RIGHT SHOULDER REPLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	14 Mar 2021 20:28:54
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 16:18:08
Data point term sent to Coder	(b) (4)	
User entered 'worsening OSTEOARTHRITIS' reason for change: Data Entry Error	Coder Import (b) (4)	23 Feb 2021 16:18:08
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'due to osteoarthritis. will add procedure to con procedures.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	System	23 Feb 2021 16:17:01
User closed query 'PV Query: Reported term is a procedure, please update event term to underlying condition.' (Site from Safety).	Sherry McCammon (b) (4)	23 Feb 2021 16:16:17
Data point term sent to Coder	(b) (4)	
	Sherry McCammon (b) (4)	23 Feb 2021 13:32:18
	(b) (4)	
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:29:54
User closed query 'PV Query: Reported term is a procedure, please update event term to underlying condition.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 17:34:48
Data point term sent to Coder	System	20 Feb 2021 15:45:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Reported term is a procedure, please update event term to underlying condition.' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	20 Feb 2021 15:45:17
Query 'For coding purposes, TOTAL RIGHT SHOULDER REPLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated' (Site from Coder).	Kaitlin Mason (b) (4)	20 Feb 2021 15:45:13
Coding entries removed.	Kaitlin Mason (b) (4)	20 Feb 2021 15:45:03
User entered 'RIGHT SHOULDER REPLACEMENT r/t osteoarthritis' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:45:03
User opened query 'PV Query: Reported term is a procedure, please update event term to underlying condition.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:51:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthropathy, LLT: Unspecified disorder of joint of shoulder region - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 13:52:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 13:52:03
User opened query 'For coding purposes, TOTAL RIGHT SHOULDER REPLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	27 Jan 2021 13:50:01
Data point term sent to Coder	System	19 Jan 2021 20:35:27
User entered 'total right shoulder replacement'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

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Generated On: 10 Jun 2021 09:30:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '12 Jan 2021'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:59:01
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Mar 2021 15:48:36
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 15:48:36
	(b) (4), (b) (6)	04 Mar 2021 15:48:36
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 15:48:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:48:36
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	04 Mar 2021 15:47:33
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:59:01
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Mar 2021 15:47:33
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Mar 2021 15:47:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 15:47:33
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 15:47:33
	(b) (4), (b) (6)	
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:47:33
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Mar 2021 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49
	(b) (4)	

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Folder: Adverse Events

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:03:20
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:50:51
User entered empty.	System	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 12:58:23
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'submitted' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 19:33:32
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:34:53
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:44:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:50:27
User entered '12 Jan 2021' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Jan 2021 20:37:00
User entered '14 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '15 Jan 2021'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Feb 2021 15:12:37
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Jan 2021 20:37:00
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:12:37
User entered '0'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Feb 2021 16:16:17
User closed query 'Per CDM: Please confirm there is no Concomitant Procedure for this AE.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	22 Feb 2021 17:41:54
Query 'Per CDM: Please confirm there is no Concomitant Procedure for this AE.' answered with 'no con procedures' (Site from DM).	Kaitlin Mason (b) (4)	20 Feb 2021 15:26:49
	(b) (4)	
User opened query 'Per CDM: Please confirm there is no Concomitant Procedure for this AE.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 13:31:01
User entered '0' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Jan 2021 20:37:00
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:59:01
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:12:57
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:48:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 15:46:25
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 15:46:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:46:25
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:28:21
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:35:03

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'ongoing' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:26:41
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Jan 2021 20:51:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4) (b) (4)	19 Jan 2021 20:34:49

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:35:16
User closed query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 17:35:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 17:35:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid testing reported' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:26:33
Query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'see conmeds' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:21:38

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No relevant lab results' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:21:25
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Jan 2021 20:51:37
User opened query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Jan 2021 20:51:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Jan 2021 20:50:37
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Jan 2021 20:37:00
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 20:37:00
User entered 'Volunteer had right shoulder replacement on 12JAN2021 and was hospitalized until 15JAN2021.' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Jan 2021 20:37:00
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	19 Jan 2021 20:34:49
	(b) (4)	

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Jan 2021 20:34:49

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 13:44:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 13:44:08
Data point term sent to Coder	System	26 Jan 2021 13:43:31
User entered 'WORSENING HYPERTENSION'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 13:42:36
User entered empty.	System	26 Jan 2021 13:42:36
	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 13:42:36
User entered empty.	System	26 Jan 2021 13:42:36
	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '12 Jan 2021'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Per MM, Please provide end date' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:43:05
Query 'Per MM, Please provide end date' answered with 'participant continues medication for exacerbation ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:46:16
User opened query 'Per MM, Please provide end date' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 17:43:36
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 13:42:36

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

US3742076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Jan 2021 13:42:36
	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Per MM, please provide the seriousness of the event, relationship and action taken with IP.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:42:53
Query 'Per MM, please provide the seriousness of the event, relationship and action taken with IP.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:46:52
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:46:43
User opened query 'Per MM, please provide the seriousness of the event, relationship and action taken with IP.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 17:43:19
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 13:42:36
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 13:42:36
User entered empty.	System	26 Jan 2021 13:42:36
	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 13:42:36
User entered empty.	System	26 Jan 2021 13:42:36
	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:30:43

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'I'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:46:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Kaitlin Mason (b) (4)	20 Feb 2021 15:46:43
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 13:42:36
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:42:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Feb 2021 15:46:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Feb 2021 15:46:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:30:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 13:31:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:31:38
Data point term sent to Coder	System	09 Sep 2020 13:30:49
User entered 'LEVOTHYROXINE'	(b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'HYPOTHYROIDISM'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '125'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 13:33:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 13:33:15
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:33:15
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 13:30:14
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:30:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:33:15
User entered empty.	System	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:33:15
User entered empty.	System	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 13:33:15
User entered empty.	System	09 Sep 2020 13:30:14

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 13:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:33:42
Data point term sent to Coder	System	09 Sep 2020 13:32:52
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'HIGH CHOLESTEROL'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '40'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'UN Mar 2017'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 13:32:49

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 13:35:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:35:52
Data point term sent to Coder	System	09 Sep 2020 13:34:56
User entered 'METOPROLOL'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '25'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'UN Mar 2017'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 13:34:36

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 14:59:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:59:38
Data point term sent to Coder	System	09 Sep 2020 13:36:58
User entered 'ASPIRIN'	(b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'PROPHYLAXIS CORONARY ARTERY DISEASE'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '81'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'UN Mar 2017'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 13:36:18

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 13:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:38:45
Data point term sent to Coder User entered 'IBUPROFEN'	System (b) (4), (b) (6)	09 Sep 2020 13:38:02 09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'OSTEOARTHRITIS'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '400'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 13:37:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
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)	13 Oct 2020 20:25:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:25:16
Data point term sent to Coder	System	13 Oct 2020 20:24:37
User entered 'flu vaccine'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'flu prevention'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0.5'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'mL (mL)'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'once (ONCE)'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '10 Oct 2020'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '10 Oct 2020'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Hassan Haji (b) (4)	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User entered empty.	System	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User entered empty.	System	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:19
User entered empty.	System	13 Oct 2020 20:24:19

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:27:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:27:51
Data point term sent to Coder	System	25 Jan 2021 16:08:10
Coding entries removed.	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
Coding entries removed.	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
User entered 'CEFAZOLIN' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
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)	25 Jan 2021 15:56:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 15:56:55
Data point term sent to Coder	System	25 Jan 2021 15:55:52
User entered 'FLU VACCINE'	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'POST OP PROPHYLAXIS' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 16:07:22
User entered 'FLU PREVENTION'	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
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	20 Feb 2021 15:10:37
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:10:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	25 Jan 2021 16:07:22
User entered '.05'	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:10:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:10:37
User entered 'g (g)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:10:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	25 Jan 2021 16:07:22
User entered 'mL (mL)'	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'three times daily (TID)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:10:37
User entered 'other (OTHER)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
User entered 'once (ONCE)'	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	20 Feb 2021 15:10:37
User entered 'EVERY 8 HOURS AS NEEDED'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
User entered '10 Oct 2020'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:07:22
User entered '10 Oct 2020'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:55:39
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User entered '3'	System	20 Feb 2021 15:10:37
User entered empty.	System	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User entered '1'	System	20 Feb 2021 15:10:37
User entered empty.	System	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:24
User entered '804 (804)'	System	20 Feb 2021 15:10:37
User entered empty.	System	25 Jan 2021 15:55:39

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:48:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:48:05
Data point term sent to Coder	System	25 Jan 2021 16:09:10
User entered 'FENTANYL' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
Data point term sent to Coder	System	25 Jan 2021 15:58:54
User entered 'CEFAZOLIN'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User closed query 'Per DM CLR: Please review AE eCRF's AE #1 TOTAL RIGHT SHOULDER REPLACEMENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:13:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Query 'Per DM CLR: Please review AE eCRF's AE #1 TOTAL RIGHT SHOULDER REPLACEMENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	20 Feb 2021 15:11:01
User opened query 'Per DM CLR: Please review AE eCRF's AE #1 TOTAL RIGHT SHOULDER REPLACEMENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:20:27
User entered 'POST OP PAIN' reason for change:	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
Data Entry Error	(b) (4)	
User entered 'POST OP PROPHYLAXIS'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '25' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
User entered '1'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
User entered 'g (g)'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'EVERY 3 HOURS AS NEEDED'	(b) (4)	
reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
User entered 'EVERY 8 HOURS'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '12 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:09:08
User entered '14 Jan 2021'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User entered empty.	System	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User entered empty.	System	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:29
User entered empty.	System	25 Jan 2021 15:58:30

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:44:30
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 09:44:30
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:57:00
Data point term sent to Coder	System	20 Feb 2021 15:14:23
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:14:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:46:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:46:03
Data point term sent to Coder	System	25 Jan 2021 16:11:11
User entered 'OXYCONDONE' reason for change:	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 16:01:03
User entered 'FENTANYL'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'POST OP PAIN'	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:14:21
User entered '5' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:14:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 16:10:57
User entered empty; reason for change Data Entry Error	System	25 Jan 2021 16:10:57
User entered '25'	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:14:21
User entered 'mg (mg)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:14:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	25 Jan 2021 16:10:57
User entered 'ug (ug)'	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	20 Feb 2021 15:14:58
User entered 'as needed (PRN)' reason for change: Data Entry Error	System	20 Feb 2021 15:14:58
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	20 Feb 2021 15:14:21
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	20 Feb 2021 15:14:21
User entered 'once (ONCE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:14:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	25 Jan 2021 16:10:57
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
	(b) (4)	
User entered 'EVERY 3 HOURS AS NEEDED'	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Feb 2021 15:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 15:14:21
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:14:21
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:10:57
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered empty.	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
User entered '12 Jan 2021'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:10:57
User entered '13 Jan 2021'	(b) (4)	
	Sherry McCammon (b) (4)	25 Jan 2021 16:00:50
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User entered empty.	System	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User entered empty.	System	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:03:36
User entered empty.	System	25 Jan 2021 16:00:50

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 22:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 22:44:55
Data point term sent to Coder	System	25 Jan 2021 16:13:12
User entered 'AMPLODIPINE' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 16:12:31
Data point term sent to Coder	System	25 Jan 2021 16:04:08
User entered 'OXYCONDONE'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 16:03:27

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'WORSENING HTN' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User entered 'POST OP PAIN'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:12:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:12:31
User entered '5' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:03:27
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:14:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	20 Feb 2021 15:15:28
User entered 'mg (mg)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Feb 2021 15:15:19
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:20:37
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:12:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:12:31
User entered 'ug (ug)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:03:27
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:12:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:12:31
User entered 'once daily (QD)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:03:27
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:12:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:12:31
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:03:27
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '14 Jan 2021'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	25 Jan 2021 16:12:31
	(b) (4)	
User entered '16 Jan 2021'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Jan 2021 16:03:27
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 16:12:31
User entered empty.	System	25 Jan 2021 16:03:27

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 16:12:31
User entered empty.	System	25 Jan 2021 16:03:27

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 16:12:31
User entered empty.	System	25 Jan 2021 16:03:27

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
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)	20 Feb 2021 15:18:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 15:18:46
Data point term sent to Coder	System	20 Feb 2021 15:17:24
User entered 'tylenol'	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:16:47

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'post operative right shoulder pain'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 15:16:47

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '1000'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'mg (mg)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'twice daily (BID)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '12 Jan 2021'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '0'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Feb 2021 15:16:47
	(b) (4)	

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Feb 2021 15:16:47

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Feb 2021 15:16:47

US3742076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Feb 2021 15:16:47

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:30:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Feb 2021 16:14:23
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Feb 2021 13:20:10
	(b) (4)	

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '12 Jan 2021'	Sherry McCammon (b) (4)	23 Feb 2021 16:15:00
	(b) (4)	

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'right should replacement for worsening osteoarthritis'	Sherry McCammon (b) (4)	23 Feb 2021 16:15:00
	(b) (4)	

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered 'Adverse Event (AE)'	Sherry McCammon (b) (4)	23 Feb 2021 16:15:00
	(b) (4)	

US3742076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:15:00
	(b) (4)	

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:30:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '20/Jan/2021 14:27'	(b) (4) System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:30:43

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)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:30:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered '22/Feb/2021 11:26'	(b) (4) System	22 Feb 2021 17:26:11

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:30:43

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)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:16:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:26:11

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:30:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:55
User entered '23/Feb/2021 15:18'	System	23 Feb 2021 21:18:52

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:30:43

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.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:25:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:46:35
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:18:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 21:18:52
Signature has been broken.	(b) (4), (b) (6)	23 Feb 2021 21:18:52
User entered '1' reason for change: New Information	(b) (4), (b) (6)	23 Feb 2021 21:18:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:16:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 17:26:40

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:30:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:25:55
User entered '05/Mar/2021 11:46'	System	05 Mar 2021 16:46:31

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:30:43

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.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:25:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:46:35
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 16:46:31

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:55
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'USA-US127-2021-MRNA-1273-P301000007'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Yes (Y)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'No (N)'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Karen'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Kotloff'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '685 W. Baltimore Street, HSF 480'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'Baltimore'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered '21201'	System	20 Jan 2021 19:25:06

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:59:00
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 12:58:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:09:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:27:10
User entered 'US'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Apr 2021 12:59:11
User entered '4'	System	05 Mar 2021 16:46:31
Signature has been broken.	System	23 Feb 2021 21:18:52
User entered '3'	System	23 Feb 2021 21:18:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:57:00
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:26:11
User entered '1'	System	20 Jan 2021 19:27:07

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:30:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered '05/Apr/2021 08:59'	(b) (4) System	05 Apr 2021 12:59:11

US3742076

Folder: SAE USA-US127-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:03:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:59:11