

US3742384 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:35:52

All time stamps listed in this document are displayed in GMT

US3742384

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:13:06

Generated On: 10 Jun 2021 09:35:52

Participant ID

US3742384

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

US3742384

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
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	False
Black	True
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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 17:50:37

Generated On: 10 Jun 2021 09:35:52

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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	30 JUN 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)	JUN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742384

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

Condition	SARCOIDOSIS
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742384

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

Condition	PNEUMONIA
Start date (dd MMM yyyy)	UN APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Height (xxx.x)	64.5 in
Weight (xxx.x)	241.0 lb
BMI (xxx.x)	40.81384 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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 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 17:50:37

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Date of assessment (dd MMM yyyy) 16 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:37

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:37

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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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 190964

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 17:50:37

Generated On: 10 Jun 2021 09:35:52

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 17:50:37

Generated On: 10 Jun 2021 09:35:52

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Temperature (xxx.x)	098.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	092 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	086 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 17:50:37

Generated On: 10 Jun 2021 09:35:52

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)	16 SEP 2020
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:23
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	096 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 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: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 09:53 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:53

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 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	08:44 (24 HR)
Collection date and time (derived)	16 SEP 2020 08:44

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:47	16 SEP 2020 08:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 10:23

PC Open Date & Time

16 SEP 2020 10:13

PC Close Date & Time

16 SEP 2020 12:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 01:49

PC Open Date & Time

16 SEP 2020 13:38

PC Close Date & Time

17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:27

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 09:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 17:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

98.1 °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

20 SEP 2020 20:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

16 SEP 2020 10:25

PC Open Date & Time

16 SEP 2020 10:13

PC Close Date & Time

16 SEP 2020 12:43

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 01:47

PC Open Date & Time

16 SEP 2020 13:38

PC Close Date & Time

17 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

17 SEP 2020 17:28

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 09:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

19 SEP 2020 17:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

20 SEP 2020 20:46

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

21 SEP 2020 17:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

22 SEP 2020 17:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:27
PC Open Date & Time	16 SEP 2020 10:13
PC Close Date & Time	16 SEP 2020 12:43

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 01:48
PC Open Date & Time	16 SEP 2020 13:38
PC Close Date & Time	17 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 ☒

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EAB) (1725)

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:28
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 09:15
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 17:44
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:46
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:32
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

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)	13 OCT 2020
Time of assessment (00:00-23:59)	07:30 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 07:30
Temperature (xxx.x)	100.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:51
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	115 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	13 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 08:19 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 08:19

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

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	07:59 (24 HR)
Collection date and time (derived)	13 OCT 2020 07:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:57	13 OCT 2020 07:57
Nasopharyngeal Swab 2	No		

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 99.2 °F

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

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

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

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

PC Time Stamp 13 OCT 2020 09:00

PC Open Date & Time 13 OCT 2020 08:39

PC Close Date & Time 13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 14 OCT 2020 08:44

PC Open Date & Time 13 OCT 2020 12:04

PC Close Date & Time 14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

97.9 °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

15 OCT 2020 07:14

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 15:57

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 19:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	17 OCT 2020 18:46
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:44

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

13 OCT 2020 09:00

PC Open Date & Time

13 OCT 2020 08:39

PC Close Date & Time

13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

14 OCT 2020 08:44

PC Open Date & Time

13 OCT 2020 12:04

PC Close Date & Time

14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

15 OCT 2020 09:46

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

15 OCT 2020 15:57

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

16 OCT 2020 19:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

17 OCT 2020 18:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

18 OCT 2020 19:02

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

19 OCT 2020 20:45

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 09:01
PC Open Date & Time	13 OCT 2020 08:39
PC Close Date & Time	13 OCT 2020 11:09

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 08:44
PC Open Date & Time	13 OCT 2020 12:04
PC Close Date & Time	14 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 09:47
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 15:57
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 19:22
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 18:47
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:02
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 ☒

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:45
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 OCT 2020 12:19

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 12:19

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 12:19
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3742384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:37

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 NOV 2020 08:40:34
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 68
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	20 NOV 2020 15:10:27
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 05:44:09
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 13:23:12
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 16:19:49

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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	18 DEC 2020 06:59:04
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 07:57:57

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 10:06:53
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 21:08:17

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

15 JAN 2021 14:15:59

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 <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 JAN 2021 15:37:52
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

29 JAN 2021 00:38:19

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 09:49:01

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

12 FEB 2021 09:40:57

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

19 FEB 2021 05:24:10

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

26 FEB 2021 12:27:58

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

05 MAR 2021 10:35:12

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

12 MAR 2021 09:45:13

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

19 MAR 2021 10:34:40

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 06:40:29

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

02 APR 2021 03:19:57

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 APR 2021 10:31:01
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

16 APR 2021 00:02:08

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

23 APR 2021 09:36:46

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

30 APR 2021 14:27:20

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 <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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 327

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

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

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

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

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

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

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 <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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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°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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 390

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

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

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

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

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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="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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2022 00:01
Patient Cloud Close Date & Time	15 NOV 2022 23:59

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3742384

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:35:52

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 09:22:25

US3742384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 17:55:49

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:47:11

Generated On: 10 Jun 2021 09:35:52

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) _____

US3742384

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 17:55:49

Generated On: 10 Jun 2021 09:35:52

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.

US3742384

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 APR 2021
Collection time (00:00-23:59)	07:14 (24 HR)
Collection date and time (derived)	23 APR 2021 07:14

US3742384

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:47:18

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742384

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:35:52

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"/>

US3742384

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:35:52

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742384

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3742384

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:49:24

Generated On: 10 Jun 2021 09:35:52

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 JAN 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>)	16 JAN 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

US3742384

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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

US3742384

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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)	16 JAN 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 08:46
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	070 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	092 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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)	16 JAN 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 09:25
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	117 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 JAN 2021

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

US3742384

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742384

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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) 16 JAN 2021

What was the treatment time? (00:00-23:59) 08:55 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 08:55

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

US3742384

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00-23:59)	08:13 (24 HR)
Collection date and time (derived)	16 JAN 2021 08:13

US3742384

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	08:17
Collection Date and Time (derived)	16 JAN 2021 08:17

US3742384

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	OLD29

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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)	15 FEB 2021
Time of assessment (00:00-23:59)	07:05 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 07:05
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	112 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:13:08

Generated On: 10 Jun 2021 09:35:52

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)	15 FEB 2021
Time of assessment (00:00-23:59)	07:48 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 07:48
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	118 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 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

US3742384

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	15 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742384

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 07:17 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 07:17

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

US3742384

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742384

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:13:09

Generated On: 10 Jun 2021 09:35:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742384

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	OLD57

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

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) _____

US3742384

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

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.

US3742384

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	07:03 (24 HR)
Collection date and time (derived)	18 MAR 2021 07:03

US3742384

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

AEID

Adverse event

BACTERIAL VAGINOSIS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

7 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 OCT 2020

Start time (00:00-23:59)

05:00 (24 HR)

AE start date and time (derived)

13 OCT 2020 05:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

13 OCT 2020 08:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

AEID	USA-US127-2020-MRNA-1273-P30 1000008
Adverse event	DIVERTICULITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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)	01 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	09 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	AS OF 08 DEC 2020, PARTICIPANT STILL WITH TEMPORARY COLOSTOMY. WILL GO BACK FOR REVERSAL.
Narrative	VOLUNTEER REPORTS BEING HOSPITALIZED FOR DIVERTICULITIS. SAE REPORTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

AEID

Adverse event

LOWER BACK MUSCLE STRAIN

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

30 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

AEID

Adverse event

INSOMNIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

AEID	
Adverse event	PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

AEID	USA-US127-2021-MRNA-1273-P30 1000014
Adverse event	REVERSAL OF OSTOMY - S/P HARTMANN'S PROCEDURE
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)	05 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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)	05 APR 2021
Hospital Discharge Date (dd MMM yyyy)	09 APR 2021
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 (7)

Generated On: 10 Jun 2021 09:35:52

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	True
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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

AEID	
Adverse event	INSOMNIA
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)	UN APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

AEID	
Adverse event	HEALTHCARE ASSOCIATED PNEUMONIA
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)	UN APR 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)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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 (9)

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:13:07

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication CHANTIX

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

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 (1)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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 DEC 2016	
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 (2)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 (2)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	30 JUN 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) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		30 JUN 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) 26 Apr 2021 14:47:10

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SARCOIDOSIS

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 (4)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (5)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication TRELEGY ELLIPTA
[FLUTICASONE,
UMECLIDINIUM, AND
VILANTEROL]

Prophylaxis Yes ☐
No ☒

Indication SARCOIDOSIS

Dose per administration 100/62.5/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication CHROMMATE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT 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 (6)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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	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 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication BACTERIAL VAGINOSIS

Dose per administration 500

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) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication B12 INJECTION

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LIPOTROPIC
[METHIONINE/INOSITOL/CHOLI
NE]

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 (9)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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) 26 Apr 2021 14:47:10

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Name of Medication BC TAB [ASPIRIN/CAFFEINE]

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 845/65

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:47:10

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 (11)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication THROMBUS PROPHYLAXIS

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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EAB) (1725)

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US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication PIPERACILLIN TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 3.375

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 (14)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication ONDANSEETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA/DIVERTICULITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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 (17)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		28 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)		28 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 (18)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 5/325

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 (19)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 10

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

If dose unit is Other, specify MEQ

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 (20)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 500

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 (21)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 5/325

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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US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
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"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication FELXERIL

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK MUSCLE STRAIN

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

BID PRN

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

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EAB) (1725)

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

QHS PRN

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 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"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (27)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication HEALTHCARE ASSOCIATED
PNEUMONIA

Dose per administration 750

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 (27)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)	10 APR 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 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication HEALTHCARE ASSOCIATED
PNEUMONIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

	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)		10 APR 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 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication REVERSAL OF OSTONOMETRY S/P
HARTMANN'S PROCEDURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:13:07

Generated On: 10 Jun 2021 09:35:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 21:47:17

Generated On: 10 Jun 2021 09:35:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
5 NOV 2020	HARTMAN'S PROCEDURE	Adverse Event	

US3742384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:35:52

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

US3742384

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:35:52

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 ☐

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	04/NOV/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 22:18
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

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:06
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

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	09/DEC/2020 14:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	11/DEC/2020 19:59
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

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:20
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

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 18:09:25

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2020-MRNA-1273-P301000008
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)	7
Date of submission (Pre-filled from custom function)	
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.	

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2021-MRNA-1273-P301000014
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)	2

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2021-MRNA-1273-P301000014
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)	2
Date of submission (Pre-filled from custom function)	12/APR/2021 12:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:47:10

Generated On: 10 Jun 2021 09:35:52

SAEID	USA-US127-2021-MRNA-1273-P301000014
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)	2
Date of submission (Pre-filled from custom function)	23/APR/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

Audit

US3742384 (Prod: University of Maryland School of Medicine)

US3742384

Form: Participant Creation

Generated On: 10 Jun 2021 09:35:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'US3742384'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 11:34:18

US3742384

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 11:34:19

US3742384

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'SCRN'	System	16 Sep 2020 13:59:23

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered (b) (6) 1980' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 14:59:36
User entered (b) (6) 1940'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 11:34:20

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:02:35
Query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' answered with 'Deviation will be reported' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	17 Nov 2020 19:39:26
User opened query 'Per CDM Re-query: Response is noted. Please confirm if deviation was reported. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:30:11
User closed query 'Age does not fit Cohort. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:29:28
Query 'Age does not fit Cohort. Please review and update. ' answered with 'Participant was randomized incorrectly. Made several data change requests but was informed that changes can not be make to stratification ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 18:01:09
User opened query 'Age does not fit Cohort. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:10:09
Query 'Age does not fit Cohort. Please review and update.' canceled (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:10:03
Comment added 'A DATA CHANGE REQUEST WAS SUBMITTED AND IT STATES IT WAS COMPLETED BUT THE COHORT HAS NOT CHANGED.'.	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 19:49:26
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 14:59:36
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	16 Sep 2020 14:00:52
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	16 Sep 2020 13:59:42
User entered '40'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'YEARS'	System	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '40'	System	16 Sep 2020 14:59:36
User entered '80'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Female (F)'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'I'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 13:59:42

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Sep 2020'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2020'	System	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:00:52

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 11:34:19

US3742384

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'I'	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:35:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:42:12

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
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)	16 Sep 2020 14:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:45:40
Data point term sent to Coder	System	16 Sep 2020 14:45:19
User entered 'HYPERTENSION'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '30 Jun 2017'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:50:48
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Jun 2017'	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2017'	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Sep 2020 14:44:59

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User coded data point as SOC: Immune system disorders, HLGT: Immune disorders NEC, HLT: Acute and chronic sarcoidosis, PT: Sarcoidosis, LLT: Sarcoidosis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:46:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 14:46:37
Data point term sent to Coder	System	16 Sep 2020 14:46:20
User entered 'SARCOIDOSIS'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33
	(b) (4)	

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'UN UNK 2019'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Jan 2019'	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2019'	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Sep 2020 14:45:33

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 15:19:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 15:19:00
Data point term sent to Coder	System	08 Dec 2020 15:18:16
User entered 'vitamin D deficiency'	Hassan Haji (b) (4)	08 Dec 2020 15:17:43
	(b) (4)	

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'UN UNK 2015'	Hassan Haji (b) (4)	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Jan 2015'	System	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2015'	System	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	08 Dec 2020 15:17:43

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:21:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:21:43
Data point term sent to Coder	System	23 Dec 2020 18:20:55
User entered 'obesity'	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'I'	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Kaitlin Mason (b) (4)	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	23 Dec 2020 18:20:14

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:25:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:25:54
Data point term sent to Coder	System	16 Mar 2021 16:24:48
User entered 'pneumonia'	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'I'	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'No (N)'	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'I'	Sherry McCammon (b) (4)	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	16 Mar 2021 16:23:51

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:25:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:25:54
Data point term sent to Coder	System	16 Mar 2021 16:24:48
User entered 'pneumonia'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'UN Apr 2019'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'No (N)'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'UN Apr 2019'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	Sherry McCammon (b) (4)	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Apr 2019'	System	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2019'	System	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'Apr 2019'	System	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '2019'	System	16 Mar 2021 16:24:28

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:18'	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Sep 2020 08:18'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '64.5' in	Hassan Haji (b) (4)	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '241.0' lb	Hassan Haji (b) (4)	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '40.81384'	System	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'kg/m2'	System	16 Sep 2020 15:05:44
DataPoint set to visible.	System	16 Sep 2020 14:00:56

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'bpm'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'breaths/min'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	16 Sep 2020 15:05:44

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19

US3742384

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19

US3742384

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:05:52

US3742384

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:05:52

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:52

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 15:06:42

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	30 Sep 2020 13:38:02
User entered 'Urine (URINE)' reason for change:	(b) (4), (b) (6)	30 Sep 2020 13:38:02
Data Entry Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 13:37:56
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	30 Sep 2020 13:37:56

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'I'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:01:42

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'VISIT1'	System	16 Sep 2020 15:07:03

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '190964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:39:55

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'per CDM: obesity is marked as yes but not present on medical history, please clarify or reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 00:02:13
Query 'per CDM: obesity is marked as yes but not present on medical history, please clarify or reconcile' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	23 Dec 2020 18:19:40
User opened query 'per CDM: obesity is marked as yes but not present on medical history, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 21:01:39
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:07:35

US3742384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:18:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:18:55

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:18'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '16 Sep 2020 08:18'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '098.9' F	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '092'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'bpm'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '12'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'breaths/min'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '127'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '086'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '10:23'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '16 Sep 2020 10:23'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '99.2' F	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '096'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'bpm'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'breaths/min'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '128'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '085'	Hassan Haji (b) (4)	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	16 Sep 2020 15:16:20

US3742384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:16:35

US3742384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:16:35

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Urine (URINE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:56:28
Query 'per CDM: please input yes or no in this field' answered with 'updateded' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 13:00:00
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 12:59:42
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 14:32:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:38:33
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered empty.	System	16 Sep 2020 15:17:27

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '09:53'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '16 Sep 2020 09:53'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'ONCE'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 14:06:16

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:44'	Hassan Haji (b) (4)	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '16 Sep 2020 08:44'	System	16 Sep 2020 15:17:54

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:35:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:47'	Hassan Haji (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '16 Sep 2020 08:47'	System	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered empty.	System	16 Sep 2020 15:18:19

US3742384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:18:40

US3742384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'I'	System	16 Sep 2020 15:18:40

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered 'Yes (Y)'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2' User entered '99.2'	System	16 Sep 2020 14:23:50
	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered 'No (N)'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:23:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5f10a47d-4710-4fc3-9c40-21dfd69064a2'	System	16 Sep 2020 14:23:50
User entered '16 Sep 2020 10:23'	System	16 Sep 2020 14:23:50

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered 'Yes (Y)'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d' User entered '97.7'	System	17 Sep 2020 05:49:03
	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered 'No (N)'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:49:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b4e56fea-c717-4741-961a-16bd1ac4763d'	System	17 Sep 2020 05:49:03
User entered '17 Sep 2020 01:49'	System	17 Sep 2020 05:49:03

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered 'Yes (Y)'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered '98.2'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered 'No (N)'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9628657f-7db9-456a-a32f-2c5290785945'	System	17 Sep 2020 21:27:48
User entered '17 Sep 2020 17:27'	System	17 Sep 2020 21:27:48

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered 'Yes (Y)'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered '98.2'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered 'No (N)'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '131c9fa5-54e2-4641-8639-ff72eaf1f92d'	System	19 Sep 2020 13:14:54
User entered '19 Sep 2020 09:14'	System	19 Sep 2020 13:14:54

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:42:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered 'Yes (Y)'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered '98.8'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered 'No (N)'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd01db338-db60-4c7b-8383-7270718c1015'	System	19 Sep 2020 21:43:26
User entered '19 Sep 2020 17:43'	System	19 Sep 2020 21:43:26

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered 'Yes (Y)'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered '98.1'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered 'No (N)'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8924a04c-9500-445c-8779-fda2c0323f12'	System	21 Sep 2020 00:45:37
User entered '20 Sep 2020 20:45'	System	21 Sep 2020 00:45:37

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:30:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered 'Yes (Y)'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:30:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered '98.7'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered 'No (N)'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '16fd6c6a-cdd7-4b0f-ac0b-c89beb632b30'	System	21 Sep 2020 21:31:10
User entered '21 Sep 2020 17:31'	System	21 Sep 2020 21:31:10

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered 'Yes (Y)'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered '98.4'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered 'No (N)'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4b0838b3-7d9c-4def-a617-b875513b9034'	System	22 Sep 2020 21:04:41
User entered '22 Sep 2020 17:04'	System	22 Sep 2020 21:04:41

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:24:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'None (1)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'No (N)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'No (N)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered 'None (1)'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:25:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '42150791-320d-492e-a7f0-6e7492eb3ecb'	System	16 Sep 2020 14:25:19
User entered '16 Sep 2020 10:25'	System	16 Sep 2020 14:25:19

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'None (1)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'No (N)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'No (N)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered 'None (1)'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d4948a-16fc-4fc0-9508-145c9cb670e9'	System	17 Sep 2020 05:47:58
User entered '17 Sep 2020 01:47'	System	17 Sep 2020 05:47:58

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'None (1)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'No (N)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'No (N)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered 'None (1)'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7393e8b8-23f8-46c9-a9f7-b2c908a4794a'	System	17 Sep 2020 21:28:40
User entered '17 Sep 2020 17:28'	System	17 Sep 2020 21:28:40

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'None (1)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'No (N)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'No (N)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '76f9b5a3-57ef-47e2-a660-68e248fc0891'	System	19 Sep 2020 13:15:50
User entered '19 Sep 2020 09:15'	System	19 Sep 2020 13:15:50

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'None (1)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:43:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'No (N)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'No (N)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered 'None (1)'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f48c3e4a-74b7-4534-b6a7-04dbfa14ade4'	System	19 Sep 2020 21:44:26
User entered '19 Sep 2020 17:44'	System	19 Sep 2020 21:44:26

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'None (1)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'No (N)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'No (N)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:45:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered 'None (1)'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '702bcf75-9ed9-440e-b4ae-0bf1c8e9e034'	System	21 Sep 2020 00:46:06
User entered '20 Sep 2020 20:46'	System	21 Sep 2020 00:46:06

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'None (1)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'No (N)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'No (N)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered 'None (1)'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bd31e728-2462-4f0f-80ca-bf5ab92f35ff'	System	21 Sep 2020 21:31:54
User entered '21 Sep 2020 17:31'	System	21 Sep 2020 21:31:54

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'None (1)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'No (N)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'No (N)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:04:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered 'None (1)'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a977443f-b8c3-41f9-af6f-b461fe43a42d'	System	22 Sep 2020 21:05:05
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:05

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'None (0)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:45', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered 'No (N)'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-16T10:27:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e57ed8b0-90f0-4692-915a-e28eea195e27'	System	16 Sep 2020 14:28:03
User entered '16 Sep 2020 10:27'	System	16 Sep 2020 14:28:03

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 10:13'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 12:43'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:47:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'None (0)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered 'No (N)'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T01:48:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f196e41e-bd1f-49c6-8146-de039e1b0fa6'	System	17 Sep 2020 05:48:19
User entered '17 Sep 2020 01:48'	System	17 Sep 2020 05:48:19

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Sep 2020 13:38'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 2'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:27:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'None (0)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered 'No (N)'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-17T17:28:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'd9bece71-4402-4ef0-aad8-f2d70c7671ec'	System	17 Sep 2020 21:28:22
User entered '17 Sep 2020 17:28'	System	17 Sep 2020 21:28:22

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 3'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'No interference with activity (1)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:14:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'None (0)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered 'No (N)'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T09:15:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'ac692baf-fa1a-4694-8f9d-a4aa56328eb5'	System	19 Sep 2020 13:15:24
User entered '19 Sep 2020 09:15'	System	19 Sep 2020 13:15:24

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 4'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:45', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'None (0)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b' User entered 'None (0)'	System	19 Sep 2020 21:44:57
	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered 'No (N)'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-19T17:44:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c6579292-8de6-40c8-8d6d-12534673d76b'	System	19 Sep 2020 21:44:57
User entered '19 Sep 2020 17:44'	System	19 Sep 2020 21:44:57

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 5'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:23', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'None (0)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered 'No (N)'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-20T20:46:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a241dce3-ebc5-41e3-bacd-cf39d42f0da3'	System	21 Sep 2020 00:46:38
User entered '20 Sep 2020 20:46'	System	21 Sep 2020 00:46:38

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 6'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4' User entered 'None (0)'	System	21 Sep 2020 21:32:25
	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:31:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4' User entered 'None (0)'	System	21 Sep 2020 21:32:25
	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'None (0)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered 'No (N)'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-21T17:32:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '5e1c36c3-4c98-4553-92a9-3f8f46da2be4'	System	21 Sep 2020 21:32:25
User entered '21 Sep 2020 17:32'	System	21 Sep 2020 21:32:25

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 7'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'None (0)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered 'No (N)'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-09-22T17:05:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '49cb7f72-0879-4f41-b74d-912d1ce121d5'	System	22 Sep 2020 21:05:21
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:21

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:06:16

US3742384

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '23 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	23 Sep 2020 15:30:53

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53

US3742384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Sherry McCammon (b) (4)	23 Sep 2020 15:30:53

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 15:31:02

US3742384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	23 Sep 2020 15:31:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:02

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:07

US3742384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	30 Sep 2020 13:37:07

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '7 Oct 2020'	Hassan Haji (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Hassan Haji (b) (4)	07 Oct 2020 19:47:53

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Oct 2020 19:47:58

US3742384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	07 Oct 2020 19:47:58

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 12:25:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 12:25:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 12:25:09
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 12:24:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'VISIT2'	System	13 Oct 2020 12:25:09
User entered empty.	System	13 Oct 2020 12:24:43

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '07:30'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '13 Oct 2020 07:30'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '100.0' F	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '108'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'bpm'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'breaths/min'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '122'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '080'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:51'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '13 Oct 2020 08:51'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '99.2' F	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Oral (Oral)'	(b) (4) Hassan Haji (b) (4) (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '115'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'bpm'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '16'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'breaths/min'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '153'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '072'	Hassan Haji (b) (4)	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'mmHg'	System	02 Nov 2020 19:22:12

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:04

US3742384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:04

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:53:16
Query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' answered with 'Date/time removed' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:37:05
User opened query 'per CDM: if FSH sample was not collected, the collection date and time fields should be blank - please use the drop down menu to remove data, or clarify' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:37:08
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:37:08
User entered '07:30'	(b) (4), (b) (6)	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered empty.	System	21 Oct 2020 20:37:08
User entered '13 Oct 2020 07:30'	System	13 Oct 2020 12:27:59

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '08:19'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '13 Oct 2020 08:19'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'ONCE'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 12:24:32

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Oct 2020 11:46:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'PER SPONSOR - OK TO USE DAY 29 LAB FOR UNSCHEDULED VISIT AS WELL. SAMPLE IS SUITABLE FOR BOTH EVENTS. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 14:08:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:13:58
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:11:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:01:24

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '07:59'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '13 Oct 2020 07:59'	System	13 Oct 2020 12:28:17

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:04:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Unscheduled Visit kit used for Day 29 visit due to shortage of Kit A at site. Confirmed that sample is for D29, NOT unscheduled visit. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	30 Oct 2020 14:56:18
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:06:53
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '07:57'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '13 Oct 2020 07:57'	System	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered empty.	System	13 Oct 2020 12:28:37

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:53:08

US3742384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '1'	System	13 Oct 2020 13:53:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered 'Yes (Y)'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '99.2'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered 'Yes (Y)'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:08:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 12:31:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '1'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '0'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4261cc8f-c035-4eb5-a2da-c6d9bb8bba8c'	System	13 Oct 2020 13:00:38
User entered '13 Oct 2020 09:00'	System	13 Oct 2020 13:00:38

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered 'Yes (Y)'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '98.2'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:43:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered 'Yes (Y)'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:09:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 12:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '1'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '0'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '59f8135c-2bc0-43d5-993e-cf6ff8ce1a39'	System	14 Oct 2020 12:44:08
User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:08

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered 'Yes (Y)'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered '97.9'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered 'No (N)'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:14:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fbfa7849-bbbc-405c-957e-f7288d191aa3'	System	15 Oct 2020 11:15:06
User entered '15 Oct 2020 07:14'	System	15 Oct 2020 11:15:06

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered 'Yes (Y)'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934' User entered '98.7'	System	15 Oct 2020 19:57:34
	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered 'No (N)'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '56c65c36-5047-433b-97e8-1b293b956934'	System	15 Oct 2020 19:57:34
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:57:34

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered 'Yes (Y)'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360' User entered '98.5'	System	16 Oct 2020 23:21:55
	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360'	System	16 Oct 2020 23:21:55
User entered 'No (N)'	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'eb2b231b-8267-49d0-8d15-228a91a24360' User entered '16 Oct 2020 19:21'	System	16 Oct 2020 23:21:55
	System	16 Oct 2020 23:21:55

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:44:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered 'Yes (Y)'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:45:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '99.1'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:45:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered 'Yes (Y)'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Ibuprofen 400mg po prn for pain.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 11:09:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Oct 2020 22:46:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '1'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '0'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '8a9274b2-fad8-4cee-9856-efbc11d9b803'	System	17 Oct 2020 22:46:12
User entered '17 Oct 2020 18:46'	System	17 Oct 2020 22:46:12

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered 'Yes (Y)'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered '98.5'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered 'No (N)'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6635cafb-ce8d-42c2-ac44-39e9eefa0533'	System	18 Oct 2020 23:01:40
User entered '18 Oct 2020 19:01'	System	18 Oct 2020 23:01:40

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered 'Yes (Y)'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered '98.3'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e'	System	20 Oct 2020 00:45:05
User entered 'No (N)'	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:44:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0a078a11-8b43-4029-b8e1-ea3617f0104e' User entered '19 Oct 2020 20:44'	System	20 Oct 2020 00:45:05
	System	20 Oct 2020 00:45:05

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'None (1)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'No (N)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:38', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'No (N)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered 'None (1)'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:42', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0c327097-7f5f-48e5-ac9a-bc4eae0d6f6b'	System	13 Oct 2020 13:00:50
User entered '13 Oct 2020 09:00'	System	13 Oct 2020 13:00:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'None (1)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'No (N)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'No (N)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered 'None (1)'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e3b38d89-068b-4304-984e-a386a356b9f7'	System	14 Oct 2020 12:44:25
User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'None (1)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'No (N)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T07:15:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'No (N)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered 'None (1)'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '07357dab-e231-446b-b00c-65b858e29fd8'	System	15 Oct 2020 13:46:50
User entered '15 Oct 2020 09:46'	System	15 Oct 2020 13:46:50

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'None (1)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'No (N)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:33', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'No (N)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered 'None (1)'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6777735a-afc9-41c4-8973-3d16ee13c1a9'	System	15 Oct 2020 19:57:44
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:57:44

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'None (1)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:21:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'No (N)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'No (N)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered 'None (1)'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '863914a6-4a6c-4c03-b2cc-00bb9ffa9a8f'	System	16 Oct 2020 23:22:18
User entered '16 Oct 2020 19:22'	System	16 Oct 2020 23:22:18

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'None (1)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'No (N)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'No (N)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered 'None (1)'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:46:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '6bda3299-2cee-4d81-a652-014c3d0117d0'	System	17 Oct 2020 22:46:25
User entered '17 Oct 2020 18:46'	System	17 Oct 2020 22:46:25

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:01:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'No (N)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:08', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'No (N)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered 'None (1)'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fba59ceb-c74f-4f3e-9323-fb593943de2e'	System	18 Oct 2020 23:02:20
User entered '18 Oct 2020 19:02'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:03', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'None (1)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'No (N)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:15', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'No (N)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:19', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered 'None (1)'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1fd36ea6-ce06-4e3b-be9f-1b595eb05afa'	System	20 Oct 2020 00:45:26
User entered '19 Oct 2020 20:45'	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'No interference with activity (1)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:00:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'None (0)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered 'No (N)'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-13T09:01:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b03ce50c-3fd6-4bc0-8de4-d592ac42593a'	System	13 Oct 2020 13:01:12
User entered '13 Oct 2020 09:01'	System	13 Oct 2020 13:01:12

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '13 Oct 2020 08:39'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '13 Oct 2020 11:09'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'No interference with activity (1)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:23', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered 'None (0)'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f'	System	14 Oct 2020 12:44:38
User entered 'No (N)'	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-14T08:44:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'beae4f15-2603-4ebb-999d-f3ad1cbe048f' User entered '14 Oct 2020 08:44'	System	14 Oct 2020 12:44:38
	System	14 Oct 2020 12:44:38

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '13 Oct 2020 12:04'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 2'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:46:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:02', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'None (0)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:05', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered 'No (N)'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T09:47:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '1392b7f6-23f2-4faa-bfe0-c10bd34efee1'	System	15 Oct 2020 13:47:16
User entered '15 Oct 2020 09:47'	System	15 Oct 2020 13:47:16

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 3'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:43', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:44', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'None (0)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered 'No (N)'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-15T15:57:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '3af31c6b-ddde-4346-ad17-d183dbf61f03'	System	15 Oct 2020 19:58:01
User entered '15 Oct 2020 15:57'	System	15 Oct 2020 19:58:01

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 4'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:29', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'None (0)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:35', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered 'No (N)'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-16T19:22:37', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a6347815-f663-447c-acd1-438676e530f0'	System	16 Oct 2020 23:22:41
User entered '16 Oct 2020 19:22'	System	16 Oct 2020 23:22:41

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 5'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:11', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:18', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'None (0)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered 'No (N)'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-17T18:47:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ff3f2ca-0ae5-4481-9229-af62914fca06'	System	17 Oct 2020 22:47:36
User entered '17 Oct 2020 18:47'	System	17 Oct 2020 22:47:36

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 6'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:21', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:24', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'None (0)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:32', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered 'No (N)'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-18T19:02:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a87627ac-552f-47ac-8e08-84004763a99c'	System	18 Oct 2020 23:02:40
User entered '18 Oct 2020 19:02'	System	18 Oct 2020 23:02:40

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	13 Oct 2020 12:24:32
User entered 'Day 7'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:31', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:39', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:40', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'None (0)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

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 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:43', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered 'No (N)'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-19T20:45:51', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c01beb63-0fce-4cd3-969d-93b64170701b'	System	20 Oct 2020 00:45:56
User entered '19 Oct 2020 20:45'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 12:24:32

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
Data entry locked.	System	20 Oct 2020 00:45:56
User entered 'Day 8'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:22', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d85670-df51-481b-a8ff-1c5d45742e17'	System	20 Oct 2020 16:19:29
User entered 'None (0)'	System	20 Oct 2020 16:19:29

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '99d85670-df51-481b-a8ff-1c5d45742e17'	System	20 Oct 2020 16:19:29
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:29

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:54
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	20 Oct 2020 00:45:56
User entered 'Day 8'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:28', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e0ea8a3e-dd40-430d-8911-d158625d8717'	System	20 Oct 2020 16:19:34
User entered 'None (0)'	System	20 Oct 2020 16:19:34

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:30', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'e0ea8a3e-dd40-430d-8911-d158625d8717'	System	20 Oct 2020 16:19:34
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:34

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 00:45:56

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
Data entry locked.	System	18 Oct 2020 23:02:20
User entered 'Day 8'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:36', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b676e880-83bb-45e8-9e00-8f99e95c8083'	System	20 Oct 2020 16:19:49
User entered 'No (N)'	System	20 Oct 2020 16:19:49
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-10-20T12:19:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b676e880-83bb-45e8-9e00-8f99e95c8083'	System	20 Oct 2020 16:19:49
User entered '20 Oct 2020 12:19'	System	20 Oct 2020 16:19:49
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 23:02:20

US3742384

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:35:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
DataPoint Activated.	System	20 Oct 2020 00:45:56
DataPoint Inactivated.	System	20 Oct 2020 00:45:26
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 23:02:20

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '20 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:40:13

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:40:21

US3742384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	20 Oct 2020 17:40:21

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:10:25

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:10:31

US3742384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	27 Oct 2020 13:10:31

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered '3 Nov 2020'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:10

US3742384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	03 Nov 2020 18:43:10

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:43:16

US3742384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:14
User entered 'I'	System	03 Nov 2020 18:43:16

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'No (N)'	Kaitlin Mason (b) (4)	04 Dec 2020 19:50:11

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	Kaitlin Mason (b) (4)	04 Dec 2020 19:50:11

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[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 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	04 Dec 2020 19:50:11

US3742384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'VISIT3'	System	04 Dec 2020 19:50:11

US3742384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:50:38
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	04 Dec 2020 18:30:08

US3742384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered '1'	System	04 Dec 2020 18:30:08

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	16 Sep 2020 14:06:16
User entered 'Day 64'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'Yes (Y)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'No (N)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:13', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'No (N)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'Yes (Y)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:26', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-16T08:40:34', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4a0ca7f8-a9f0-4ed3-aabe-e78fd1c55303'	System	16 Nov 2020 13:40:52
User entered '16 Nov 2020 08:40:34'	System	16 Nov 2020 13:40:52

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	16 Sep 2020 14:06:16
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 14:06:16

US3742384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:49:56
Data entry locked.	System	16 Sep 2020 14:06:16
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 14:06:16

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:25', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered 'No (N)'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:20', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered 'No (N)'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-20T15:10:27', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '27bf21fe-49b3-4d35-8175-52b49fb678c5'	System	20 Nov 2020 20:10:34
User entered '20 Nov 2020 15:10:27'	System	20 Nov 2020 20:10:34

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-11-27T05:43:55', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '86d4a392-c02b-4396-97e7-33fc531e0465'	System	27 Nov 2020 10:44:14
User entered 'No (N)'	System	27 Nov 2020 10:44:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-11-27T05:43:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '86d4a392-c02b-4396-97e7-33fc531e0465'	System	27 Nov 2020 10:44:14
User entered 'No (N)'	System	27 Nov 2020 10:44:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-11-27T05:44:09', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '86d4a392-c02b-4396-97e7-33fc531e0465'	System	27 Nov 2020 10:44:14
User entered '27 Nov 2020 05:44:09'	System	27 Nov 2020 10:44:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-12-04T13:23:07', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '30bbaca9-6b4b-49ce-aca1-50f10e0b44c6'	System	04 Dec 2020 18:23:20
User entered 'No (N)'	System	04 Dec 2020 18:23:20

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-12-04T13:23:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '30bbaca9-6b4b-49ce-aca1-50f10e0b44c6'	System	04 Dec 2020 18:23:20
User entered 'No (N)'	System	04 Dec 2020 18:23:20

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-12-04T13:23:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '30bbaca9-6b4b-49ce-aca1-50f10e0b44c6'	System	04 Dec 2020 18:23:20
User entered '04 Dec 2020 13:23:12'	System	04 Dec 2020 18:23:20

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-12-11T16:19:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '2b404d04-daf9-4498-b8a1-e1147ed964cd'	System	11 Dec 2020 21:19:53
User entered 'No (N)'	System	11 Dec 2020 21:19:53

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-12-11T16:19:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '2b404d04-daf9-4498-b8a1-e1147ed964cd'	System	11 Dec 2020 21:19:53
User entered 'No (N)'	System	11 Dec 2020 21:19:53

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-12-11T16:19:49', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '2b404d04-daf9-4498-b8a1-e1147ed964cd' User entered '11 Dec 2020 16:19:49'	System	11 Dec 2020 21:19:53
	System	11 Dec 2020 21:19:53

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-12-18T06:58:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '98a5dd87-eef5-4b4f-ab27-dd4eba4d5644'	System	18 Dec 2020 11:59:08
User entered 'No (N)'	System	18 Dec 2020 11:59:08

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-12-18T06:59:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '98a5dd87-eef5-4b4f-ab27-dd4eba4d5644'	System	18 Dec 2020 11:59:08
User entered 'No (N)'	System	18 Dec 2020 11:59:08

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-12-18T06:59:04', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '98a5dd87-eef5-4b4f-ab27-dd4eba4d5644'	System	18 Dec 2020 11:59:08
User entered '18 Dec 2020 06:59:04'	System	18 Dec 2020 11:59:08

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2020-12-25T07:57:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bfc5776f-151e-405c-816d-f6ea9b6848ed'	System	25 Dec 2020 12:58:01
User entered 'No (N)'	System	25 Dec 2020 12:58:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2020-12-25T07:57:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bfc5776f-151e-405c-816d-f6ea9b6848ed'	System	25 Dec 2020 12:58:01
User entered 'No (N)'	System	25 Dec 2020 12:58:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2020-12-25T07:57:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'bfc5776f-151e-405c-816d-f6ea9b6848ed' User entered '25 Dec 2020 07:57:57'	System	25 Dec 2020 12:58:01
	System	25 Dec 2020 12:58:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-01-01T10:06:46', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c8afc4be-f918-4fbc-b024-5b4376b3649d'	System	01 Jan 2021 15:06:57
User entered 'No (N)'	System	01 Jan 2021 15:06:57

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-01-01T10:06:50', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c8afc4be-f918-4fbc-b024-5b4376b3649d'	System	01 Jan 2021 15:06:57
User entered 'No (N)'	System	01 Jan 2021 15:06:57

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-01-01T10:06:53', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'c8afc4be-f918-4fbc-b024-5b4376b3649d' User entered '01 Jan 2021 10:06:53'	System	01 Jan 2021 15:06:57

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-01-08T21:08:12', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9eec8840-33eb-45e1-b5ac-a97a933ba822'	System	09 Jan 2021 02:08:21
User entered 'No (N)'	System	09 Jan 2021 02:08:21

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-01-08T21:08:14', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9eec8840-33eb-45e1-b5ac-a97a933ba822'	System	09 Jan 2021 02:08:21
User entered 'No (N)'	System	09 Jan 2021 02:08:21

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-01-08T21:08:17', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9eec8840-33eb-45e1-b5ac-a97a933ba822'	System	09 Jan 2021 02:08:21
User entered '08 Jan 2021 21:08:17'	System	09 Jan 2021 02:08:21

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-01-15T14:15:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fdc1d484-05f8-4018-8c73-5dd1b3c31d7a'	System	15 Jan 2021 19:16:02
User entered 'No (N)'	System	15 Jan 2021 19:16:02

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-01-15T14:15:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fdc1d484-05f8-4018-8c73-5dd1b3c31d7a'	System	15 Jan 2021 19:16:02
User entered 'No (N)'	System	15 Jan 2021 19:16:02

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-01-15T14:15:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'fdc1d484-05f8-4018-8c73-5dd1b3c31d7a'	System	15 Jan 2021 19:16:02
User entered '15 Jan 2021 14:15:59'	System	15 Jan 2021 19:16:02

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-01-23T15:37:41', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b5855c71-cc60-4d3b-8fef-668edb3ad052'	System	23 Jan 2021 20:37:54
User entered 'No (N)'	System	23 Jan 2021 20:37:54

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-01-23T15:37:47', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b5855c71-cc60-4d3b-8fef-668edb3ad052'	System	23 Jan 2021 20:37:54
User entered 'No (N)'	System	23 Jan 2021 20:37:54

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-01-23T15:37:52', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'b5855c71-cc60-4d3b-8fef-668edb3ad052'	System	23 Jan 2021 20:37:54
User entered '23 Jan 2021 15:37:52'	System	23 Jan 2021 20:37:54

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-01-29T00:38:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7199acfb-7cb1-4ecd-8487-d92b4688e877'	System	29 Jan 2021 05:38:23
User entered 'No (N)'	System	29 Jan 2021 05:38:23

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-01-29T00:38:16', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7199acfb-7cb1-4ecd-8487-d92b4688e877'	System	29 Jan 2021 05:38:23
User entered 'No (N)'	System	29 Jan 2021 05:38:23

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-01-29T00:38:19', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '7199acfb-7cb1-4ecd-8487-d92b4688e877'	System	29 Jan 2021 05:38:23
User entered '29 Jan 2021 00:38:19'	System	29 Jan 2021 05:38:23

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-02-05T09:48:48', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '09aa05d5-8cd8-475f-945f-56574b20ce33'	System	05 Feb 2021 14:49:06
User entered 'No (N)'	System	05 Feb 2021 14:49:06

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-02-05T09:48:58', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '09aa05d5-8cd8-475f-945f-56574b20ce33'	System	05 Feb 2021 14:49:06
User entered 'No (N)'	System	05 Feb 2021 14:49:06

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-02-05T09:49:01', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '09aa05d5-8cd8-475f-945f-56574b20ce33'	System	05 Feb 2021 14:49:06
User entered '05 Feb 2021 09:49:01'	System	05 Feb 2021 14:49:06

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-02-12T09:40:54', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '43101f1d-31f0-48e3-ac67-bacea8dae019'	System	12 Feb 2021 14:41:01
User entered 'No (N)'	System	12 Feb 2021 14:41:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-02-12T09:40:56', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '43101f1d-31f0-48e3-ac67-bacea8dae019'	System	12 Feb 2021 14:41:01
User entered 'No (N)'	System	12 Feb 2021 14:41:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-02-12T09:40:57', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '43101f1d-31f0-48e3-ac67-bacea8dae019'	System	12 Feb 2021 14:41:01
User entered '12 Feb 2021 09:40:57'	System	12 Feb 2021 14:41:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-02-19T05:23:59', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '84fcf98a-14d1-483d-8f03-62076457b690'	System	19 Feb 2021 10:24:14
User entered 'No (N)'	System	19 Feb 2021 10:24:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-02-19T05:24:06', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '84fcf98a-14d1-483d-8f03-62076457b690'	System	19 Feb 2021 10:24:14
User entered 'No (N)'	System	19 Feb 2021 10:24:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-02-19T05:24:10', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '84fcf98a-14d1-483d-8f03-62076457b690'	System	19 Feb 2021 10:24:14
User entered '19 Feb 2021 05:24:10'	System	19 Feb 2021 10:24:14

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-02-26T12:27:51-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a89f219f-be3d-4325-ba5a-abefa2b01ec4'	System	26 Feb 2021 17:29:36
User entered 'No (N)'	System	26 Feb 2021 17:29:36

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-02-26T12:27:56-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a89f219f-be3d-4325-ba5a-abefa2b01ec4'	System	26 Feb 2021 17:29:36
User entered 'No (N)'	System	26 Feb 2021 17:29:36

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-02-26T12:27:58-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'a89f219f-be3d-4325-ba5a-abefa2b01ec4'	System	26 Feb 2021 17:29:36
User entered '26 Feb 2021 12:27:58'	System	26 Feb 2021 17:29:36

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-03-05T10:35:07-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0af242cf-8309-4013-b6e9-01f7de68df64'	System	05 Mar 2021 15:35:15
User entered 'No (N)'	System	05 Mar 2021 15:35:15

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-03-05T10:35:10-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0af242cf-8309-4013-b6e9-01f7de68df64'	System	05 Mar 2021 15:35:15
User entered 'No (N)'	System	05 Mar 2021 15:35:15

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-05T10:35:12-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '0af242cf-8309-4013-b6e9-01f7de68df64'	System	05 Mar 2021 15:35:15
User entered '05 Mar 2021 10:35:12'	System	05 Mar 2021 15:35:15

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-03-12T09:45:03-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ca4c018-4614-48c9-b87c-57ece24da4e1' User entered 'No (N)'	System	12 Mar 2021 14:45:19
	System	12 Mar 2021 14:45:19

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-03-12T09:45:08-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ca4c018-4614-48c9-b87c-57ece24da4e1'	System	12 Mar 2021 14:45:19
User entered 'No (N)'	System	12 Mar 2021 14:45:19

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-12T09:45:13-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '4ca4c018-4614-48c9-b87c-57ece24da4e1' User entered '12 Mar 2021 09:45:13'	System	12 Mar 2021 14:45:19
	System	12 Mar 2021 14:45:19

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-03-19T10:33:44-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '226d406d-ed10-4465-bdf4-96e93b2965dd'	System	19 Mar 2021 14:34:43
User entered 'No (N)'	System	19 Mar 2021 14:34:43

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-03-19T10:34:38-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '226d406d-ed10-4465-bdf4-96e93b2965dd'	System	19 Mar 2021 14:34:43
User entered 'No (N)'	System	19 Mar 2021 14:34:43

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-19T10:34:40-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '226d406d-ed10-4465-bdf4-96e93b2965dd'	System	19 Mar 2021 14:34:43
User entered '19 Mar 2021 10:34:40'	System	19 Mar 2021 14:34:43

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-03-26T06:40:19-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '14778af1-fe54-49bf-a5c3-234072a1d61f' User entered 'No (N)'	System	26 Mar 2021 10:40:35
	System	26 Mar 2021 10:40:35

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-03-26T06:40:27-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '14778af1-fe54-49bf-a5c3-234072a1d61f' User entered 'No (N)'	System	26 Mar 2021 10:40:35
	System	26 Mar 2021 10:40:35

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-26T06:40:29-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '14778af1-fe54-49bf-a5c3-234072a1d61f' User entered '26 Mar 2021 06:40:29'	System	26 Mar 2021 10:40:35
	System	26 Mar 2021 10:40:35

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-02T03:19:46-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '95780640-85b0-496b-9a10-93e513a5844b'	System	02 Apr 2021 07:20:05
User entered 'No (N)'	System	02 Apr 2021 07:20:05

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-04-02T03:19:55-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '95780640-85b0-496b-9a10-93e513a5844b'	System	02 Apr 2021 07:20:05
User entered 'No (N)'	System	02 Apr 2021 07:20:05

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-04-02T03:19:57-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '95780640-85b0-496b-9a10-93e513a5844b'	System	02 Apr 2021 07:20:05
User entered '02 Apr 2021 03:19:57'	System	02 Apr 2021 07:20:05

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-09T10:29:41-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '06d77cba-3cce-42bc-800f-3cbf8592fb58'	System	09 Apr 2021 14:31:11
User entered 'Yes (Y)'	System	09 Apr 2021 14:31:11

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-04-09T10:29:24-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '06d77cba-3cce-42bc-800f-3cbf8592fb58'	System	09 Apr 2021 14:31:11
User entered 'No (N)'	System	09 Apr 2021 14:31:11

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-09T10:29:23-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '06d77cba-3cce-42bc-800f-3cbf8592fb58'	System	09 Apr 2021 14:31:11
User entered 'No (N)'	System	09 Apr 2021 14:31:11

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-09T10:30:56-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '06d77cba-3cce-42bc-800f-3cbf8592fb58'	System	09 Apr 2021 14:31:11
User entered 'No (N)'	System	09 Apr 2021 14:31:11

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-04-09T10:31:01-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '06d77cba-3cce-42bc-800f-3cbf8592fb58'	System	09 Apr 2021 14:31:11
User entered '09 Apr 2021 10:31:01'	System	09 Apr 2021 14:31:11

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-16T00:02:01-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '066df147-488a-44f5-811e-4044d16d795a' User entered 'No (N)'	System	16 Apr 2021 04:03:01
	System	16 Apr 2021 04:03:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-04-16T00:02:05-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '066df147-488a-44f5-811e-4044d16d795a'	System	16 Apr 2021 04:03:01
User entered 'No (N)'	System	16 Apr 2021 04:03:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-04-16T00:02:08-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '066df147-488a-44f5-811e-4044d16d795a'	System	16 Apr 2021 04:03:01
User entered '16 Apr 2021 00:02:08'	System	16 Apr 2021 04:03:01

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-23T09:36:38-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '312a3fad-c11c-421d-8dd3-d0679a5d6261' User entered 'No (N)'	System	23 Apr 2021 13:36:49
	System	23 Apr 2021 13:36:49

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-04-23T09:36:43-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '312a3fad-c11c-421d-8dd3-d0679a5d6261'	System	23 Apr 2021 13:36:49
User entered 'No (N)'	System	23 Apr 2021 13:36:49

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-04-23T09:36:46-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '312a3fad-c11c-421d-8dd3-d0679a5d6261'	System	23 Apr 2021 13:36:49
User entered '23 Apr 2021 09:36:46'	System	23 Apr 2021 13:36:49

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[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 (d06fb84cf1d8da2d)', Time: '2021-04-30T14:27:16-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f38c9e4c-ac09-40fa-a48d-d4d0c5e2b9e5'	System	30 Apr 2021 18:27:24
User entered 'No (N)'	System	30 Apr 2021 18:27:24

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

Have you been exposed to someone with 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 (d06fb84cf1d8da2d)', Time: '2021-04-30T14:27:18-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f38c9e4c-ac09-40fa-a48d-d4d0c5e2b9e5'	System	30 Apr 2021 18:27:24
User entered 'No (N)'	System	30 Apr 2021 18:27:24

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-04-30T14:27:20-04:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: 'f38c9e4c-ac09-40fa-a48d-d4d0c5e2b9e5'	System	30 Apr 2021 18:27:24
User entered '30 Apr 2021 14:27:20'	System	30 Apr 2021 18:27:24

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 08:50:07

US3742384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:07
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 08:50:07

US3742384

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:35:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:15:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-03T09:22:21-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9b5c958e-330b-4240-b85f-4e3b50c42e41'	System	03 Mar 2021 14:22:28
User entered 'No (N)'	System	03 Mar 2021 14:22:28

US3742384

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:35:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:15:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d06fb84cf1d8da2d)', Time: '2021-03-03T09:22:25-05:00', User OID: 'PatientReportedOutcome (US3742384)', ODM File OID: '9b5c958e-330b-4240-b85f-4e3b50c42e41' User entered '03 Mar 2021 09:22:25'	System	03 Mar 2021 14:22:28
	System	03 Mar 2021 14:22:28

US3742384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Dec 2020 15:22:47

US3742384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '8 Dec 2020'	Hassan Haji (b) (4)	08 Dec 2020 15:22:47

US3742384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	08 Dec 2020 15:22:47

US3742384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 15:22:47

US3742384

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Dec 2020 15:23:01

US3742384

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:47:21
User entered 'I'	System	08 Dec 2020 15:23:01

US3742384

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	13 Jan 2021 15:32:33

US3742384

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '11 Jan 2021'	Sherry McCammon (b) (4)	13 Jan 2021 15:32:33

US3742384

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	13 Jan 2021 15:32:33

US3742384

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:32:33

US3742384

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	13 Jan 2021 15:32:38

US3742384

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User entered 'I'	System	13 Jan 2021 15:32:38

US3742384

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	11 Feb 2021 17:23:55

US3742384

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10 Feb 2021'	Sherry McCammon (b) (4)	11 Feb 2021 17:23:55

US3742384

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	11 Feb 2021 17:23:55

US3742384

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	11 Feb 2021 17:23:55

US3742384

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	11 Feb 2021 17:24:02

US3742384

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:00:36
User entered 'I'	System	11 Feb 2021 17:24:02

US3742384

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	16 Mar 2021 16:22:00
	(b) (4)	

US3742384

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User entered '12 Mar 2021'	Sherry McCammon (b) (4)	16 Mar 2021 16:22:00
	(b) (4)	

US3742384

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	16 Mar 2021 16:22:00
	(b) (4)	

US3742384

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	16 Mar 2021 16:22:00
	(b) (4)	

US3742384

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	16 Mar 2021 16:22:21
	(b) (4)	

US3742384

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:50
User entered 'I'	System	16 Mar 2021 16:22:21

US3742384

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:50:12

US3742384

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:49
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:50:12

US3742384

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:50:12

US3742384

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 16:50:12

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:14:24

US3742384

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:51:15

US3742384

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:55:49
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:51:15

US3742384

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 12:36:27
Query 'Data is required. Please complete.' answered with 'Entered by error' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 16:11:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 16:10:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 16:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 16:09:47

US3742384

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User entered '23 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 16:10:48
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 16:09:47

US3742384

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User entered '07:14' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:15:44
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 16:10:48
User entered '07:03'	(b) (4), (b) (6)	18 Mar 2021 16:09:47

US3742384

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User entered '23 Apr 2021 07:14'	System	23 Apr 2021 18:15:44
User entered empty.	System	18 Mar 2021 16:10:48
User entered '18 Mar 2021 07:03'	System	18 Mar 2021 16:09:47

US3742384

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 12:36:23
Query 'Data is required. Please complete.' answered with 'Entered by error' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 16:11:33
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 16:11:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 16:11:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 16:09:59

US3742384

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 16:11:23
User entered '1'	System	18 Mar 2021 16:09:59

US3742384

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:08

US3742384

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:08

US3742384

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:08

US3742384

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:41:08

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:58:32
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:58:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:58:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:29:59

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:58:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:29:59

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '1'	System	20 Jan 2021 16:42:14

US3742384

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'I'	System	20 Jan 2021 16:42:14

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	20 Jan 2021 16:46:06
DataPoint set to visible.	System	20 Jan 2021 16:42:14

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	20 Jan 2021 16:46:06
DataPoint set to visible.	System	20 Jan 2021 16:42:14

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '08:46'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Jan 2021 08:46'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '070'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'bpm'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'breaths/min'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '149'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '092'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	20 Jan 2021 16:46:06
DataPoint set to visible.	System	20 Jan 2021 16:42:14

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '09:25'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Jan 2021 09:25'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '117'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'bpm'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '20'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'breaths/min'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '144'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '082'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:46:06

US3742384

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mmHg'	System	20 Jan 2021 16:46:06

US3742384

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:14

US3742384

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:14

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:52

US3742384

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered empty.	System	20 Jan 2021 16:42:52

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

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)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'mRNA-1273'	System	20 Jan 2021 16:43:55
DataPoint set to visible.	System	20 Jan 2021 16:42:14

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '08:55'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Jan 2021 08:55'	System	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'ONCE'	System	20 Jan 2021 16:43:55

US3742384

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

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 16:43:55

US3742384

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:32

US3742384

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:32

US3742384

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '08:13'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:32

US3742384

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Jan 2021 08:13'	System	20 Jan 2021 16:41:32

US3742384

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:46

US3742384

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:46

US3742384

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '08:17'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:41:46

US3742384

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '16 Jan 2021 08:17'	System	20 Jan 2021 16:41:46

US3742384

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

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:42:36

US3742384

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

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:19:19
User entered '1'	System	20 Jan 2021 16:42:36

US3742384

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:52:51

US3742384

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '25 Jan 2021'	Sherry McCammon (b) (4)	15 Feb 2021 18:52:51

US3742384

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	15 Feb 2021 18:52:51

US3742384

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	15 Feb 2021 18:52:51

US3742384

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:52:55

US3742384

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User entered 'I'	System	15 Feb 2021 18:52:55

US3742384

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:42
User entered '1'	System	15 Feb 2021 18:52:55
DataPoint set to visible.	System	15 Feb 2021 18:52:55

US3742384

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:54:20

US3742384

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:54:20

US3742384

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[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 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	15 Feb 2021 18:54:20

US3742384

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'OLD29'	System	15 Feb 2021 18:54:20

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01
	(b) (4)	

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '07:05'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered '15 Feb 2021 07:05'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '098.5' F	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Other (Other)'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'temporal'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '112'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'bpm'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '16'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'breaths/min'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '134'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'mmHg'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '083'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'mmHg'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01
	(b) (4)	

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '07:48'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered '15 Feb 2021 07:48'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '098.6' F	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Other (Other)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'temporal'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '118'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'bpm'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '18'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'breaths/min'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '130'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'mmHg'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '078'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'mmHg'	System	15 Feb 2021 18:57:01

US3742384

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:29

US3742384

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 18:57:29

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Urine (URINE)'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Negative (NEGATIVE)'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:51:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4) Kaitlin Mason (b) (4)	23 Feb 2021 15:15:09
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:59:17
User entered 'No (N)'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 15:15:03
User entered '15 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 15:15:03
User entered '07:08'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered empty.	System	23 Feb 2021 15:15:03
User entered '15 Feb 2021 07:08'	System	15 Feb 2021 18:59:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

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 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'mRNA-1273'	System	15 Feb 2021 18:58:04
DataPoint set to visible.	System	15 Feb 2021 18:52:55

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '07:17'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered '15 Feb 2021 07:17'	System	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Left Arm (LEFT ARM)'	Sherry McCammon (b) (4)	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'ONCE'	System	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 18:58:04

US3742384

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 18:59:10

US3742384

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:22:31
User entered 'I'	System	15 Feb 2021 18:59:10

US3742384

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	22 Feb 2021 19:23:24

US3742384

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '22 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	22 Feb 2021 19:23:24

US3742384

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	22 Feb 2021 19:23:24

US3742384

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	22 Feb 2021 19:23:24

US3742384

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Feb 2021 19:23:34

US3742384

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:47
User entered 'I'	System	22 Feb 2021 19:23:34

US3742384

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:11:58

US3742384

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '18 Mar 2021'	(b) (4)	18 Mar 2021 16:11:58
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:11:58

US3742384

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered 'OLD57'	System	18 Mar 2021 16:11:58

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered empty.	System	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered empty.	System	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered empty.	System	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered empty.	System	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:09
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered empty.	System	18 Mar 2021 16:14:09

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21

US3742384

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21

US3742384

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'No (N)'	(b) (4)	18 Mar 2021 16:14:17
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	18 Mar 2021 16:14:17
	(b) (4), (b) (6)	

US3742384

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:33

US3742384

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:33

US3742384

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '07:03'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:14:33

US3742384

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:21
User entered '18 Mar 2021 07:03'	System	18 Mar 2021 16:14:33

US3742384

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:35:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:52:15
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:34:35

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial vaginosis, LLT: Bacterial vaginosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:38:23
Data point term sent to Coder	System	13 Oct 2020 17:37:07
User entered 'bacterial vaginosis'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User entered empty.	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:38:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '15 Oct 2020' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:38:13
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User entered empty.	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:45:19
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 21:25:24
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:25:00
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:37:44
User entered '1'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:25:00
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:38:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:36:22
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User entered '0'	System	13 Oct 2020 17:36:22

US3742384

Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12
User entered '0'	System	13 Oct 2020 17:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:08:29
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
Query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' answered with 'This is an AE due to the headache occurring prior to vaccination #2.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:35:49
User opened query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Note that solicited reactions are only to reported as AE if it meets AE reporting criteria per protocol. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:37:58
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:39:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:39:26
Data point term sent to Coder	System	13 Oct 2020 17:38:08
User entered 'headache'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '05:00'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User entered '13 Oct 2020 05:00'	System	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '08:00'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User entered '13 Oct 2020 08:00'	System	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

US3742384

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:08:36
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 14:37:45
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	18 Nov 2020 14:37:40
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 06:38:04
User entered '1'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	18 Nov 2020 14:37:40
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:37:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:37:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:42
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:37:34
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User entered '0'	System	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17
User entered '0'	System	13 Oct 2020 17:37:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:11:17

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 20:35:52
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 20:35:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:27
User entered	System	04 Nov 2020 15:47:21
'USA-US127-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:47:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:24
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 18:50:59
User entered 'DIVERTICULITIS'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '01 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Un-verified.	Hassan Haji (b) (4)	08 Dec 2020 15:20:25
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4)	08 Dec 2020 15:20:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Un-verified.	Hassan Haji (b) (4)	08 Dec 2020 15:20:25
	(b) (4)	
User entered '9 Nov 2020' reason for change: New Information	Hassan Haji (b) (4)	08 Dec 2020 15:20:25
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:51:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Participant is recovering ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:42:18
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:36:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:12:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:13:26
User entered empty.	System	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4)	
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'safety report form has been entered' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:00:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	Kaitlin Mason (b) (4)	19 Nov 2020 19:00:14
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:12:13
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Event is ongoing; participant is currently hospitalized so no discharge date available.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:12:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 19:28:59
	System	03 Nov 2020 18:50:58
	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '01 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Nov 2020 20:00:49
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Nov 2020 20:00:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 19:29:32
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		03 Nov 2020 19:29:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:29:32
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 18:55:23
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:55:23
	(b) (4)	
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 18:51:34
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		03 Nov 2020 18:51:34
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:51:34
	(b) (4)	
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	03 Nov 2020 18:50:58
User entered 'Unknown (UNK)'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

US3742384

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:55:19
User entered '0' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:55:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '1'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:33:41
DataPoint Un-verified.	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:55:19
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:55:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for AE. Please reconcile with ConProc eCRF and update indication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:32:39
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for AE. Please reconcile with ConProc eCRF and update indication as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:36:13
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for AE. Please reconcile with ConProc eCRF and update indication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:35:15
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:36:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 14:55:22
DataPoint Un-verified.	Kaitlin Mason (b) (4)	23 Feb 2021 14:55:16
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 14:55:16
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:09:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered '0'	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:48:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:35:43
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'entered ' (Site from Safety).	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:20:45
DataPoint Un-verified.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:20:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:20:25
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:13:16
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:51:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Participant was discharged Nov 9 2020 but is still experiencing ongoing recovery ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 14:41:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4)	12 Nov 2020 18:35:06
	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:53:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error DataPoint Verified.	Sherry McCammon (b) (4) (b) (4) (b) (4), (b) (6)	10 Nov 2020 19:53:43 10 Nov 2020 18:50:58
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:29:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:29:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:29:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 18:50:58

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Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	11 Dec 2020 16:01:12
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 16:01:12
	(b) (4), (b) (6)	11 Dec 2020 16:01:12
User entered 'As of 08 Dec 2020, participant still with temporary colostomy. Will go back for reversal.' reason for change: New Information		
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	11 Dec 2020 15:48:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'PV Query: Please include the relevant labs results in the SAE CRF in the EDC as per 30 Nov 2020 query answer text.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:59:37
Query 'PV Query: Please include the relevant labs results in the SAE CRF in the EDC as per 30 Nov 2020 query answer text.' answered with 'Lab results received from hospital. Lab results maintained in participant's CRF.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 16:02:56
User opened query 'PV Query: Please include the relevant labs results in the SAE CRF in the EDC as per 30 Nov 2020 query answer text.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 16:50:04
User closed query 'Safety Medical Query: Please clarify if the subject had any prior episodes of diverticulitis.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 13:23:49
User closed query 'PV Query: Please provide any RELEVANT laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 13:23:44
Query 'PV Query: Please provide any RELEVANT laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'relevant labs included in SAE report ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	30 Nov 2020 19:14:55
Query 'Safety Medical Query: Please clarify if the subject had any prior episodes of diverticulitis.' answered with 'Medical history does not include any prior episodes of diverticulitis ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	30 Nov 2020 19:13:57
User opened query 'Safety Medical Query: Please clarify if the subject had any prior episodes of diverticulitis.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:13:36
User opened query 'PV Query: Please provide any RELEVANT laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:13:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	19 Nov 2020 18:05:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:52:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:52:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Participant was hospitalized for over a week. Please specify labs requested if desired.' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:46:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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 'Medications were added to conmeds and entered into SAE report ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:40:42
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 'SARS-CoV-2 Genexpert testing conducted November 1st and was not detected ' (Site from Safety).	Kaitlin Mason (b) (4)	18 Nov 2020 14:40:20

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	12 Nov 2020 18:35:53
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)	12 Nov 2020 18:34:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:34:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:54:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 18:54:18
User entered 'VOLUNTEER REPORTS BEING HOSPITALIZED FOR DIVERTICULITIS. SAE REPORTED.' reason for change: Data Entry Error	Sherry McCammon (b) (4)	03 Nov 2020 18:54:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:50:58
User entered empty.	Sherry McCammon (b) (4)	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 18:50:58

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Low back strain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 15:40:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 15:40:02
Data point term sent to Coder	System	13 Jan 2021 15:38:49
User entered 'LOWER BACK MUSCLE STRAIN'	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Dec 2020'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User entered empty.	System	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '30 Dec 2020'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User entered empty.	System	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Form: Adverse Events (4)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:16:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Jan 2021 17:16:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:38:14
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:16:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Jan 2021 17:16:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:38:14
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Generated On: 10 Jun 2021 09:35:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:16:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	20 Jan 2021 17:16:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:38:14
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'I'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:38:14
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User entered '0'	System	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	(b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
User entered '1'	System	13 Jan 2021 15:38:14
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (4)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:52
DataPoint activated with code reason code Data required.	Sherry McCammon (b) (4)	13 Jan 2021 15:37:04
DataPoint inactivated with code reason code Data not required.	Sherry McCammon (b) (4)	10 Dec 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 15:45:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 15:45:08
Data point term sent to Coder	System	13 Jan 2021 15:44:55
User entered 'INSOMNIA'	Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User entered empty.	System	13 Jan 2021 15:44:04

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '4 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User entered empty.	System	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:17:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Jan 2021 17:17:50
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:44:04
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:44:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:17:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	20 Jan 2021 17:17:50
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:44:04
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:44:04
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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 Jan 2021 17:17:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	20 Jan 2021 17:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:44:04
User entered empty.	Sherry McCammon (b) (4)	13 Jan 2021 15:44:04
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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Form: Adverse Events (5)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:44:04

US3742384

Folder: Adverse Events

Form: Adverse Events (5)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User entered '0'	System	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56
User entered 'I'	System	13 Jan 2021 15:44:04

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Folder: Adverse Events

Form: Adverse Events (5)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:47:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 14:00:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 14:00:02
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 13:57:49
User entered 'PNEUMONIA'	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:03:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:03:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:03:04
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Apr 2021 14:18:57
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:18:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Apr 2021 13:57:49
User entered 'UN Nov 2020' (non-conformant).	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:57:49

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:02:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:02:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:02:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:02:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:02:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:18:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:18:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:18:57
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 14:02:36

US3742384

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 13:57:49

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:37
User entered 'USA-US127-2021-mRNA-1273-P301000014'	System	12 Apr 2021 18:56:57
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 18:56:57

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for informing that participant had ostomy reversal after complications of AE 3 diverticulitis. Please consider updating the event term to the underlying cause of the event.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:41:14
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colostomy, LLT: Hartmann's pouch procedure - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 19:58:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 19:58:32
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:03:57
Data point term sent to Coder	System	20 Apr 2021 21:06:47
User closed query 'For coding purposes, REVERSAL OF OSTOMY - S/P HARTMANN'S PROCEDURE 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 System).	System	20 Apr 2021 21:06:07
Query 'For coding purposes, REVERSAL OF OSTOMY - S/P HARTMANN'S PROCEDURE 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 'Participant had ostomy reversal after complications of AE 3 diverticulitis ' (Site from System).	Kaitlin Mason (b) (4)	20 Apr 2021 21:06:07
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Participant had ostomy reversal after complications of AE 3 diverticulitis ' (Site from Safety).	Kaitlin Mason (b) (4)	20 Apr 2021 21:05:44

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, REVERSAL OF OSTOMY - S/P HARTMANN'S PROCEDURE 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 System).	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:00:31
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:45:00
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	09 Apr 2021 18:33:45
Data point term sent to Coder	System	09 Apr 2021 18:30:30
User entered 'Reversal of ostomy - S/P Hartmann's Procedure'	(b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 12:45:25
User entered 'Yes (Y)'	Milagritos Tapia (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 18:33:45 09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 08:54:26
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Start date is entered still being hospitalized.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 18:31:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:30:17
User entered '1'	(b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 17:42:31
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 11:57:21
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	23 Apr 2021 11:56:50
User entered '09 Apr 2021' reason for change: New Information	(b) (4)	
	Kaitlin Mason (b) (4)	23 Apr 2021 11:56:50
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:45:54
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	23 Apr 2021 19:15:05
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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 'medications added' (Site from Safety). Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	23 Apr 2021 11:57:40
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	23 Apr 2021 11:56:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. 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)	19 Apr 2021 12:46:22
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	09 Apr 2021 18:33:45
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:46:10
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:15:01
User closed query 'PV Query: Please provide dates and results of CT scan and chest x-ray.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:14:58
User closed query 'PV Query: Please confirm if AE pneumonia is prolonging hospital stay. If it is please consider adding pneumonia as SAE. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:14:55
User closed query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:14:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records send 4/22/21' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 11:56:27
Query 'PV Query: Please provide dates and results of CT scan and chest x-ray.' answered with 'results sent 4/22/2021. CTA chest 4/7/2021 showed no evidence of PE but did not small areas of groundglass consolidations in LUL and BLL and subsegmental atelectasis in BLL. portable CXR done 4/7/21 showed mild vague opacity at L lung base and mild RLL subsegmental atelectasis versus scarring ' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 11:55:10
Query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' answered with 'participant tested negative for sars cov 2 on 02APR2021' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 11:50:49
Query 'PV Query: Please confirm if AE pneumonia is prolonging hospital stay. If it is please consider adding pneumonia as SAE. ' answered with 'PNA did not prolong hospital stay. Participant d/c on po abx' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 11:49:43
User closed query 'PV Query: Please consider diverticulitis to the subject's medical history if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:04:29
Query 'PV Query: Please consider diverticulitis to the subject's medical history if applicable. ' answered with 'added as AE' (Site from Safety).	Kaitlin Mason (b) (4)	20 Apr 2021 21:06:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:48:52
User opened query 'PV Query: Please confirm if AE pneumonia is prolonging hospital stay. If it is please consider adding pneumonia as SAE. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:48:38
User opened query 'PV Query: Please consider diverticulitis to the subject's medical history if applicable. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:47:19
User opened query 'PV Query: Please provide dates and results of CT scan and chest x-ray.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:47:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:46:36
User signature succeeded.	Milagritos Tapia (b) (4)	09 Apr 2021 18:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:30:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:30:17

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 19:27:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 19:27:56
Data point term sent to Coder	System	23 Apr 2021 19:27:36
User entered 'INSOMNIA'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	24 Apr 2021 16:09:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 19:27:09
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 19:27:09

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Healthcare associated pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 19:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 19:38:23
Data point term sent to Coder	System	23 Apr 2021 19:36:48
User entered 'HEALTHCARE ASSOCIATED PNEUMONIA'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	24 Apr 2021 16:09:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 19:36:10
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 19:36:10

US3742384

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:35:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 19:36:10

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:35:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:46:58

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 14:50:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 14:50:38
Data point term sent to Coder	System	16 Sep 2020 14:49:25
User entered 'chantix'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:34:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'no medical condition.' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:41:54
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:58:31
User entered 'smoking cessation'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '1'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'as needed (PRN)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '12 Dec 2016'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:48:39
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:48:39

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 14:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:52:40
Data point term sent to Coder	System	16 Sep 2020 14:51:32
User entered 'hydrochlorothiazide'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'hypertension'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '12.5'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '30 Jun 2017'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:50:36
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:50:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 14:54:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:54:38
Data point term sent to Coder User entered 'losartan'	System Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:53:38 16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'hypertension'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '50'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '30 Jun 2017'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:53:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:53:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 14:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:59:43
Data point term sent to Coder	System	16 Sep 2020 14:58:48
User entered 'prednisone'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'sarcoidosis'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:01:38
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:59:32
User entered '5'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'as needed (PRN)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'UN Jul 2019'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:57:56
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 14:57:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 12:05:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:05:47
Data point term sent to Coder	System	07 Dec 2020 20:32:13
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 20:31:18
User entered 'TRELEGY ELLIPTA [Fluticasone, umeclidinium, and vilanterol]' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 20:31:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:00:44
Data point term sent to Coder	System	16 Sep 2020 14:59:53
User entered 'trelegy ellipta'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location or type of SARCOIDOSIS. Please reconcile with Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:03:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please update the indication to reflect the location or type of SARCOIDOSIS. Please reconcile with Med History eCRFs as appropriate. ' answered with 'appears to be lung but will confirm with participant' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:15:34
User opened query 'Per DM CLR: Please update the indication to reflect the location or type of SARCOIDOSIS. Please reconcile with Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:15:31
User entered 'sarcoidosis'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only two components were reported in the dose field. Please update the dose to include three components as applicable (e.g. 100/62.5/25).' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:13:02
Query 'Per DM CLR: Please note, this is a combination drug; however, only two components were reported in the dose field. Please update the dose to include three components as applicable (e.g. 100/62.5/25).' ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 20:31:28
User entered '100/62.5/25' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 20:31:18
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only two components were reported in the dose field. Please update the dose to include three components as applicable (e.g. 100/62.5/25).' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:12:59
User entered '100-62.5'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:55:04
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	06 Oct 2020 19:55:17
User entered 'ug (ug)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	06 Oct 2020 19:55:11
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:29:50
User entered 'Other (OTHER)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	06 Oct 2020 19:55:11
	(b) (4)	
User entered 'mcg'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'UN UNK 2019'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 14:59:33
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 14:59:33

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: CHROMIUM NICOTINATE;NICOTINIC ACID, PRODUCTSYNONYM: CHROMEMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 02:59:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:59:00
Data point term sent to Coder Coding entries removed.	System Hassan Haji (b) (4)	23 Oct 2020 18:58:09 23 Oct 2020 18:57:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: CHROMIUM NICOTINATE;NICOTINIC ACID, PRODUCTSYNONYM: CHROMEMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:32:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:32:55
Data point term sent to Coder User entered 'chrommate'	System Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:04:02 16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:46:19
Query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:40:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 15:40:01
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded suggests medication was given as a prophylaxis. Please review and update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:56:01
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'SUPPLEMENT prophylaxis' reason for change: Data Entry Error	Hassan Haji (b) (4)	23 Oct 2020 18:57:41
	(b) (4)	
User entered 'supplement'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '1'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'tablet (TABLET)'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'UN Jan 2018'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 15:03:44
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:03:44

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:27:46
Data point term sent to Coder	System	20 Oct 2020 17:26:37
User entered 'METRONIDAZOLE'	Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'BACTERIAL VAGINOSIS'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '500'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'twice daily (BID)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '08 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User entered '2'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User entered '1'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:47
User entered '804 (804)'	System	20 Oct 2020 17:26:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:31:44
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:19:58
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 23:19:58
Data point term sent to Coder	System	25 Jan 2021 20:19:01
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 20:18:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:22:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:22:25
Data point term sent to Coder	System	20 Oct 2020 17:28:41
User entered 'B12 INJECTION'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:23:14
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:18:52
User entered 'OBESITY' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 20:18:39
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:56:43
User entered 'WEIGHT LOSS'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:24:00
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' answered with 'UPDATED TO UG'S' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:19:13
User entered '1000' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 20:18:39
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:56:33
User entered '2'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:18:39
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'every week (QS)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '02 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:28:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:28:21
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:21
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:28:16
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:28:16
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	20 Oct 2020 17:28:16

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: CHOLINE;INOSITOL;METHIONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 10:09:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 10:09:23
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 20:21:02
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 20:20:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: CHOLINE;INOSITOL;METHIONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 05:06:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 05:06:31
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 17:33:53
User entered 'LIPOTROPIC [METHIONINE/INOSITOL/CHOLINE]'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:24:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:21:04
User entered 'OBESITY' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:20:26
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:57:43
User entered 'WEIGHT LOSS'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '1'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Other (OTHER)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'INJECTION'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '02 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:33:08
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:33:08

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: BC [ACETYLSALICYLIC ACID;CAFFEINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 09:52:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:52:27
Data point term sent to Coder	System	20 Oct 2020 17:36:00
User entered 'BC TAB [ASPIRIN/CAFFEINE]'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'HEADACHE'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '845/65'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once (ONCE)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '13 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '13 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User closed query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:03:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:16:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 15:16:08
User opened query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:07:40
User entered 'No (N)'	Kaitlin Mason (b) (4)	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:04
User entered empty.	System	20 Oct 2020 17:35:28

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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)	20 Oct 2020 17:37:40
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 Oct 2020 17:37:40
Data point term sent to Coder User entered 'IBUPROFEN'	System Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:37:03 20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:04:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'did not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:19:15

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:58:22
User entered 'HEADACHE'	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '400'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'as needed (PRN)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '13 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '17 Oct 2020'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	(b) (4) Kaitlin Mason (b) (4)	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:35:52
User entered empty.	System	20 Oct 2020 17:36:32

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 15:10:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:10:32
Data point term sent to Coder	System	10 Nov 2020 19:46:36
User entered 'LOVENOX'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'THROMBUS PROPHYLAXIS'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '40'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '01 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 14:29:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '9 Nov 2020' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 14:29:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User entered '1'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User entered '1'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:14
User entered '804 (804)'	System	10 Nov 2020 19:45:36

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 15:08:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:08:32
Data point term sent to Coder	System	10 Nov 2020 19:48:38
User entered 'KETOROLAC'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'DIVERTICULITIS'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '30'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '02 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 14:30:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '9 Nov 2020' reason for change: New Information	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:30:31
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:47:47
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User entered '1'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User entered '1'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:23
User entered '804 (804)'	System	10 Nov 2020 19:47:47

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Nov 2020 06:57:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:57:15
Data point term sent to Coder	System	10 Nov 2020 19:49:39
User entered 'PIPERACILLIN TAZOBACTAM'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'DIVERTICULITIS'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '3.375'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'g (g)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '01 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4)	08 Dec 2020 14:31:21
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '9 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:31:21
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User entered '1'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User entered '1'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:25
User entered '804 (804)'	System	10 Nov 2020 19:48:59

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:04:59
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:13:10
Data point term sent to Coder	System	23 Feb 2021 15:22:25
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	23 Feb 2021 15:21:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:00:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:00:39
Data point term sent to Coder	System	10 Nov 2020 19:50:41
User entered 'ONDANSEETRON'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:04:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'associated with AE 3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:21:42
User entered 'NAUSEA/diverticulitis' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 15:21:28
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:59:22
User entered 'NAUSEA'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '4'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'as needed (PRN)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Intravenous (INTRAVENOUS)'	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '01 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 14:32:08
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '9 Nov 2020' reason for change: New Information	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:32:08
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:50:21
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:27
User entered empty.	System	10 Nov 2020 19:50:21

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:04:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'associated with AE #3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:22:29
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 22:01:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:07:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:07:39
Data point term sent to Coder	System	10 Nov 2020 19:51:42
User entered 'LABETALOL'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'HYPERTENSION'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'as needed (PRN)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '02 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4)	08 Dec 2020 14:33:41
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '9 Nov 2020' reason for change: New Information	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:33:41
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	10 Nov 2020 19:51:26
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:32
User entered empty.	System	10 Nov 2020 19:51:26

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 19:53:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:53:41
Data point term sent to Coder	System	10 Nov 2020 19:52:44
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4) (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0.5'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mL (mL)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once (ONCE)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '28 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '28 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:47
User entered empty.	System	10 Nov 2020 19:52:19

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Dec 2020 14:42:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:42:31
Data point term sent to Coder	System	08 Dec 2020 14:41:32
User entered 'vitamin D3'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:41:22

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'vitamin D deficiency'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '50'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'ug (ug)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'UN UNK 2015'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	08 Dec 2020 14:41:22
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:41:22

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:41:22

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 14:41:22

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 14:45:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:45:03
Data point term sent to Coder	System	08 Dec 2020 14:43:33
User entered 'hydrocodone/APAP'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User closed query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:06:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' answered with 'associated with con procedure/AE3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:23:04
User opened query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:08:36
User entered 'POST-OP PAIN'	Hassan Haji (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '5/325'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '27 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:33:40
User entered 'Yes (Y)'	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:43:14
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	13 Jan 2021 15:33:40
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 14:43:14
	(b) (4)	

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	Hassan Haji (b) (4)	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User entered '1'	System	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User entered '1'	System	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:52
User entered '804 (804)'	System	08 Dec 2020 14:43:14

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 14:54:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:54:57
Data point term sent to Coder	System	08 Dec 2020 14:53:43
User entered 'potassium chloride'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User closed query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:06:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' answered with 'associated with hospitalization with AE 3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:25:24
User opened query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:13:01
User entered 'hypokalemia'	Hassan Haji (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage with the corresponding dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:06:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage with the corresponding dose unit as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:25:05
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage with the corresponding dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:13:16
User entered '10'	Hassan Haji (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit with the appropriate dose for this Con Med. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Milagritos Tapia (b) (4)	08 Apr 2021 04:17:32 07 Apr 2021 21:47:18
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit with the appropriate dose for this Con Med. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:43:14
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:43:05
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:43:05
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for the dose recorded. Please update the unit with the appropriate dose for this Con Med. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Karen Kotloff (b) (4)	17 Mar 2021 12:18:11 23 Feb 2021 18:13:10
User entered 'ug (ug)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 15:24:58
User entered 'mg (mg)'	Hassan Haji (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:43:05
User entered 'MEQ' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:43:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	Hassan Haji (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '13 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User entered '1'	System	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User entered '1'	System	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:54
User entered '804 (804)'	System	08 Dec 2020 14:53:13

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 15:08:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:08:55
Data point term sent to Coder	System	08 Dec 2020 15:07:57
User entered 'Levaquin'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User closed query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:07:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' answered with 'associated with AE #3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:25:52
User opened query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:10:03
User entered 'pneumonia'	Hassan Haji (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '500'	Hassan Haji (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '17 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User entered '1'	System	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User entered '1'	System	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:36:59
User entered '804 (804)'	System	08 Dec 2020 15:07:53

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 23:55:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:55:44
Data point term sent to Coder	System	08 Dec 2020 15:10:04
User entered 'Percocet'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User closed query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:07:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' answered with 'associated with AE3' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:26:01
User opened query 'Per DM CLR: Please note that there is no AE condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:12:17
User entered 'post-op pain'	Hassan Haji (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '5/325'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10 Nov 2020'	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '25 Nov 2020'	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User entered '1'	System	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User entered '1'	System	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:01
User entered '804 (804)'	System	08 Dec 2020 15:09:20

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:15:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:15:03
Data point term sent to Coder	System	08 Dec 2020 15:14:10
User entered 'metronidazole'	Hassan Haji (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User closed query 'Per DM CLR: Con Med start date (10 NOV 2020) is after the stop date of the corresponding AE condition (9 NOV 2020). Please review Con Med use and reconcile with AE eCRF. Update indication, start/stop dates or add a medical condition that matches this indication in AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:07:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Query 'Per DM CLR: Con Med start date (10 NOV 2020) is after the stop date of the corresponding AE condition (9 NOV 2020). Please review Con Med use and reconcile with AE eCRF. Update indication, start/stop dates or add a medical condition that matches this indication in AE eCRF as appropriate. ' answered with 'start and stop dates are correct and per participant report and medical records ' (Site from DM).	Kaitlin Mason (b) (4)	23 Feb 2021 15:26:46
User opened query 'Per DM CLR: Con Med start date (10 NOV 2020) is after the stop date of the corresponding AE condition (9 NOV 2020). Please review Con Med use and reconcile with AE eCRF. Update indication, start/stop dates or add a medical condition that matches this indication in AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:11:22
User entered 'diverticulitis'	Hassan Haji (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '500'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'three times daily (TID)'	(b) (4) Hassan Haji (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '10 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '17 Nov 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User entered '3'	System	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User entered '1'	System	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:08
User entered '804 (804)'	System	08 Dec 2020 15:13:56

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 15:38:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 15:38:02
Data point term sent to Coder	System	13 Jan 2021 15:35:45
User entered 'FELXERIL'	Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'LOWER BACK MUSCLE STRAIN'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '5'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'BID PRN'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '30 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User entered empty.	System	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User entered empty.	System	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:18
User entered empty.	System	13 Jan 2021 15:35:06

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Jan 2021 15:38:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:38:02
Data point term sent to Coder User entered 'AMBIEN'	System Sherry McCammon (b) (4) (b) (4)	13 Jan 2021 15:36:46 13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'INSOMNIA'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '5'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'QHS PRN'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Oral (ORAL)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '15 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered '0'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:38:01
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:11:15
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 15:11:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 15:11:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 05:37:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:11:08
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 15:11:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered empty.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User entered empty.	System	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User entered empty.	System	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:37:19
User entered empty.	System	13 Jan 2021 15:36:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 17:31:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:31:01
Data point term sent to Coder	System	23 Apr 2021 17:29:44
User entered 'AMBIEN'	(b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'UN Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:29:25

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Apr 2021 12:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:24:47
Data point term sent to Coder	System	23 Apr 2021 17:33:49
User entered 'LEVOFLOXACIN'	(b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'HEALTHCARE ASSOCIATED PNEUMONIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '750'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 17:33:09

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 11:13:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 11:13:43
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 17:37:00
User entered 'DOXYCYCLINE'	(b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'HEALTHCARE ASSOCIATED PNEUMONIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 17:36:05

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Apr 2021 12:44:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:44:56
Data point term sent to Coder	System	23 Apr 2021 19:39:50
Data point term sent to Coder	System	23 Apr 2021 17:47:07
User entered 'TRAMADOL'	(b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'REVERSAL OF OSTONOMY S/P HARTMANN'S PROCEDURE' reason for change:	(b) (4)	
New Information	(b) (4), (b) (6)	23 Apr 2021 19:38:51
User entered 'POST-OPERATIVE PAIN'	(b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '50'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'EVERY 4 HOURS AS NEEDED'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 19:38:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 19:38:51
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 19:38:51
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 17:46:35
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'UN Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:35:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:46:35

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:35:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
User entered 'Yes (Y)'	Hassan Haji (b) (4)	08 Dec 2020 15:14:39

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:52

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5 Nov 2020'	Hassan Haji (b) (4)	08 Dec 2020 15:15:54
	(b) (4)	

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'Hartman's procedure'	Hassan Haji (b) (4)	08 Dec 2020 15:15:54
	(b) (4)	

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure corresponding AE's Other Action Taken include 'Concomitant Procedure'.', otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:33:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	05 Apr 2021 13:35:50
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure corresponding AE's Other Action Taken include 'Concomitant Procedure'.', otherwise clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:35:27
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	05 Apr 2021 13:35:16
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:35:16
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:35:16
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure corresponding AE's Other Action Taken include 'Concomitant Procedure'.', otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:55:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:13:10

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:52

[Indication](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:15:54

US3742384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:35:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:35:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered 'diverticulitis'	Hassan Haji (b) (4)	08 Dec 2020 15:15:54
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered '04/Nov/2020 10:48'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered '11/Nov/2020 22:18'	System	11 Nov 2020 22:18:39

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 22:18:39

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered '19/Nov/2020 18:06'	System	19 Nov 2020 18:06:04

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:06:04

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:01:47
User entered '09/Dec/2020 14:37'	System	09 Dec 2020 20:37:12

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 20:37:12

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:01:47
User entered '11/Dec/2020 19:59'	System	11 Dec 2020 19:59:58

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:20:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:01:47
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 19:59:58

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:04
User entered '24/Feb/2021 11:20'	System	24 Feb 2021 16:20:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:29:04
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:44:12
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:20:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:29:04
User entered '24/Feb/2021 11:44'	System	24 Feb 2021 16:44:33

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:47:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:29:04
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:44:33

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered		
'USA-US127-2020-MRNA-1273-P301000008'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Yes (Y)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'No (N)'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Karen'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Kotloff'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '685 W. Baltimore Street, HSF 480'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered 'Baltimore'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:01:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:59:48
DataPoint Un-verified.	System	09 Dec 2020 20:37:12
User entered empty.	System	09 Dec 2020 20:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:54
User entered 'MD' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 18:03:18
Un-reviewed for Safety.	System	19 Nov 2020 18:06:04
DataPoint Un-verified.	System	19 Nov 2020 18:06:04
User entered empty.	System	19 Nov 2020 18:06:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:34:45
User entered 'Maryland'	Kaitlin Mason (b) (4)	18 Nov 2020 14:24:44
	(b) (4)	

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:51:39
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:47:51
User entered '21201'	System	04 Nov 2020 15:47:21

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:39
User entered 'US'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	24 Feb 2021 16:44:33
Signature has been broken.	System	24 Feb 2021 16:20:21
User entered '6'	System	24 Feb 2021 16:20:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:13:10
	(b) (4)	
User entered '5'	System	11 Dec 2020 19:59:58
User entered '4'	System	09 Dec 2020 20:37:12
User entered '3'	System	19 Nov 2020 18:06:04
User entered '2'	System	11 Nov 2020 22:18:39
User entered '1'	System	04 Nov 2020 15:48:02

US3742384

Folder: SAE USA-US127-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:09:25
User entered empty.	Milagritos Tapia (b) (4)	30 Apr 2021 18:07:39

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'USA-US127-2021-MRNA-1273-P301000014'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Karen'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Kotloff'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '685 W. Baltimore Street, HSF 480'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Baltimore'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '21201'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered 'US'	(b) (4) System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 18:26:02
User entered '1'	System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'USA-US127-2021-MRNA-1273-P301000014'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Karen'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Kotloff'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '685 W. Baltimore Street, HSF 480'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Baltimore'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '21201'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered 'US'	(b) (4) System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 18:26:02
User entered '1'	System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered '12/Apr/2021 12:04'	(b) (4) System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:02:56

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'USA-US127-2021-MRNA-1273-P301000014'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Yes (Y)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'No (N)'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Karen'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Kotloff'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '685 W. Baltimore Street, HSF 480'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered 'Baltimore'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:39
User entered '21201'	System	12 Apr 2021 18:56:57

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:25
User entered 'US'	(b) (4) System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 18:26:02
User entered '1'	System	12 Apr 2021 19:04:32

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered '23/Apr/2021 11:26'	(b) (4) System	23 Apr 2021 18:26:02

US3742384

Folder: SAE USA-US127-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:47:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:26:02