

US3742330 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:32:31

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US3742330

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:02:08

Generated On: 10 Jun 2021 09:32:31

[Participant ID](#)

US3742330

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

US3742330

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

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 17:44:33

Generated On: 10 Jun 2021 09:32:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742330

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742330

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	FLUID RETENTION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742330

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	SINUS CONGESTION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742330

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	NEPHRECTOMY (R)
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3742330

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Condition	STAGE 2 RENAL INSUFFICIENCY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:09
Height (xxx.x)	67.0 in
Weight (xxx.x)	305.0 lb
BMI (xxx.x)	47.86964 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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 17:44:33

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Date of assessment (dd MMM yyyy) 11 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) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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

CURCH VOLUNTEER EXPOSURE
TO GRANDCHILDREN

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 17:44:33

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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 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 190675

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 17:44:33

Generated On: 10 Jun 2021 09:32:31

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 17:44:33

Generated On: 10 Jun 2021 09:32:31

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)	11 SEP 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:09
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

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)	11 SEP 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:58
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 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 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

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

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	11 SEP 2020 10:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:13	11 SEP 2020 10:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

11 SEP 2020 12:08

PC Open Date & Time

11 SEP 2020 11:42

PC Close Date & Time

11 SEP 2020 14:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	11 SEP 2020 22:12
PC Open Date & Time	11 SEP 2020 15:07
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

96.8 °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

12 SEP 2020 22:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

13 SEP 2020 22:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

95.8 °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

14 SEP 2020 22:43

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 SEP 2020 22:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

96.2 °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 08:52

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:09

PC Open Date & Time

11 SEP 2020 11:42

PC Close Date & Time

11 SEP 2020 14:12

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

11 SEP 2020 22:13

PC Open Date & Time

11 SEP 2020 15:07

PC Close Date & Time

12 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

12 SEP 2020 22:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

13 SEP 2020 22:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

14 SEP 2020 22:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

15 SEP 2020 22:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

17 SEP 2020 08:52

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

17 SEP 2020 22:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 12:09
PC Open Date & Time	11 SEP 2020 11:42
PC Close Date & Time	11 SEP 2020 14:12

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:13
PC Open Date & Time	11 SEP 2020 15:07
PC Close Date & Time	12 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:04
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

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EAB) (1725)

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2964

EAB) (1725)

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:44
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

EAB) (1725)

57 of 2964

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:03
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 08:52
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 ☒

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EAB) (1725)

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3742330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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)	9 OCT 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 11:30
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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)	9 OCT 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:55
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	059 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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) 9 OCT 2020

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

Treatment Date and Time (derived) 9 OCT 2020 12:23

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

US3742330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	9 OCT 2020 11:38

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:37	9 OCT 2020 11:37
Nasopharyngeal Swab 2	No		

US3742330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

09 OCT 2020 13:29

PC Open Date & Time

09 OCT 2020 12:43

PC Close Date & Time

09 OCT 2020 15:13

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 09:20

PC Open Date & Time

09 OCT 2020 16:08

PC Close Date & Time

10 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

98.1 °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

10 OCT 2020 22:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

11 OCT 2020 22:43

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 22:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 23:21

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

14 OCT 2020 22:05

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 22:04

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

09 OCT 2020 13:29

PC Open Date & Time

09 OCT 2020 12:43

PC Close Date & Time

09 OCT 2020 15:13

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

10 OCT 2020 09:20

PC Open Date & Time

09 OCT 2020 16:08

PC Close Date & Time

10 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

10 OCT 2020 22:28

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

11 OCT 2020 22:45

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

12 OCT 2020 22:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

13 OCT 2020 23:22

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

14 OCT 2020 22:05

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

15 OCT 2020 22:04

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 13:30
PC Open Date & Time	09 OCT 2020 12:43
PC Close Date & Time	09 OCT 2020 15:13

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

No ☒

Yes ☐

PC Time stamp	10 OCT 2020 09:20
PC Open Date & Time	09 OCT 2020 16:08
PC Close Date & Time	10 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 22:28
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

99 of 2964

EAB) (1725)

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 22:45
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

101 of 2964

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 22:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 23:22
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 22:05
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 ☒

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 22:04
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3742330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

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) _____

US3742330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3742330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 NOV 2020

Collection time (00:00-23:59)

10:58 (24 HR)

Collection date and time (derived)

6 NOV 2020 10:58

US3742330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:44:33

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 13:51:35

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 17:47:14

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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	23 NOV 2020 10:01:34
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 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	30 NOV 2020 15:01:19
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 DEC 2020 10:41:43
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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	16 DEC 2020 12:04:26
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

24 DEC 2020 09:42:41

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 10:18:43

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

07 JAN 2021 09:27:20

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

14 JAN 2021 11:50:40

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:03:58

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

27 JAN 2021 09:18:42

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

03 FEB 2021 22:08:14

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

17 FEB 2021 08:46:31

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

25 FEB 2021 13:49:03

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

02 MAR 2021 09:29:52

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

10 MAR 2021 09:04:12

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

18 MAR 2021 09:06:16

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 11:27:07
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

31 MAR 2021 09:17:44

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 09:20:27

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

15 APR 2021 14:04:32

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

22 APR 2021 10:22:08

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

29 APR 2021 10:54:16

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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"/>

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3742330

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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) _____

US3742330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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.

US3742330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

10:17 (24 HR)

Collection date and time (derived)

24 MAR 2021 10:17

US3742330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Date of Contact 23 SEP 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☐

Convalescent Tele-visit ☒

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:02:09

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Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	098.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	097.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	097.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	096.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	30 SEP 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3742330

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:00
Height (xxx.x)	68.0 in
Weight (xxx.x)	307.6 lb
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	063 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742330

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3742330

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3742330

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

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

Visit date (dd MMM yyyy)	14 JAN 2021
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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	UNBLND_DECIDE
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US3742330

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 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

US3742330

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

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

US3742330

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

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)	14 JAN 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 09:21
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	054 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	068 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

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)	14 JAN 2021
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:08
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	060 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)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3742330

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 09:38

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

US3742330

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	14 JAN 2021 08:55

US3742330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	08:59
Collection Date and Time (derived)	14 JAN 2021 08:59

US3742330

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

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)	11 FEB 2021
Time of assessment (00:00-23:59)	09:11 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:11
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

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)	11 FEB 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:55
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	068 mmHg
Diastolic Blood Pressure units	MMHG

US3742330

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3742330

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

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) 11 FEB 2021

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

Treatment Date and Time (derived) 11 FEB 2021 09:24

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

US3742330

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742330

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742330

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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) _____

US3742330

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

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.

US3742330

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	24 MAR 2021 10:17

US3742330

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:02:08

Generated On: 10 Jun 2021 09:32:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID

Adverse event

NASAL CONGESTION

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)

23 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 SEP 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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID

Adverse event

SINUS 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)

22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 SEP 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID

Adverse event

LEFT ARM PAIN FROM
SEASONAL FLU INJECTION

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)

27 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)

27 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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID	USA-US127-2020-MRNA-1273-P30 1000012
Adverse event	ACUTE HYPOXEMIC RESPIRATORY FAILURE
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)	28 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)	03 DEC 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)	29 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	03 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (5)

Data signed: (b) (4) 14 Mar 2021 21:35:20

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

PARTICIPANT REPORTS
SHORTNESS OF BREATH WITH
SELF REPORTED HYPOXEMIA
BEGINNING NOVEMBER 28
2020. PARTICIPANT WENT TO
PRIMARY DOCTOR AT KAISER
PERMANENTE NOVEMBER
29TH WHERE SHE TESTED
NEGATIVE FOR SARS-COV-2.
WAS TRANSFERRED TO
INPATIENT CARE LATE
NOVEMBER 29TH WHERE SHE
IS UNDERGOING EVALUATION
FOR PROBABLE CONGESTIVE
HEART FAILURE. PARTICIPANT
HAD CHEST CT 29 NOV THAT
SHOWED BILATERAL PLEURAL
EFFUSIONS BUT NO SIGNS OF
COVID INFECTION. LAB
VALUES REPORTED ARE
WITHIN NORMAL LIMITS AND
PARTICIPANT STARTED
COURSE OF IV LASIX AND
HOSPITAL ANTICOAGULATION.

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 (6)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID	
Adverse event	DIASTOLIC CONGESTIVE HEART FAILURE
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)	26 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 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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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 (7)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID	
Adverse event	ATRIAL FIBRILATION
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)	03 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (7)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

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	True
Concomitant Medication	False
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 (8)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

AEID	
Adverse event	ARTERIOSKLEROSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 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	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

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	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Mar 2021 21:35:20

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AEID

Adverse event

CHRONIC KIDNEY DISEASE

STATE 3

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)

3 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)

27 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 ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Mar 2021 21:35:20

Generated On: 10 Jun 2021 09:32:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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 checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PARTICIPANT HAS REACHED NEW BASELINE - CKD CONTINUES BUT IS STABLE
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)	0

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

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) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication AMLOPDIPINE

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 (1)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100QAM, 50QPM

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) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (3)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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)	5 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 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 (5)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 1985
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29	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 (6)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION

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 (6)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 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 (7)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication NYQUIL (650 MG.
ACETAMINOPHEN, 30 MG.
DEXTROMETHORPHAN, 12.5
MG. DOXYLAMINE)

Prophylaxis Yes ☐
No ☒

Indication NASAL CONGESTION

Dose per administration 2

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 (7)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication SINUS HEADACHE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 OCT 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 (9)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SINUS HEADACHE

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 (9)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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)		9 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) 9 OCT 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 (10)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication RENAL INSUFFICIENCY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT ARM PAIN FROM
SEASONAL INFLUENZA
VACCINE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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)	27 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)		27 OCT 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 (12)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication HIGH DOSE INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.7

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 (12)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intraocular	<input type="radio"/>
	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)	27 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)		27 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 (13)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXEMIC
RESPIRATORY FAILURE

Dose per administration 80

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 (13)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 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)	30 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)	03 DEC 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 (14)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication DABIGATRAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 150

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) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 NOV 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)		2
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 (15)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXEMIC
RESPIRATORY FAILURE

Dose per administration 1

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

If dose unit is Other, specify LITER

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 (15)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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)	3 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
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 (16)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication CORTICOSTEROID INJECTION
RIGHT KNEE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (16)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	6 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	6 JAN 2021	
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 (17)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication CORTICOSTEROID INJECTION
LEFT KNEE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (17)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTERARTICULAR	
Start date (dd MMM yyyy)	6 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	6 JAN 2021	
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) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION

Dose per administration 200

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

If dose unit is Other, specify MCG

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) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 DEC 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)		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 (19)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	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 NOV 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)		2
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 (21)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication ALDACTONE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	19 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

Name of Medication ALDACTONE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

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 (22)

Data signed: (b) (4) 13 Apr 2021 21:47:22

Generated On: 10 Jun 2021 09:32:31

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:02:09

Generated On: 10 Jun 2021 09:32:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 21:37:51

Generated On: 10 Jun 2021 09:32:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 DEC 2020	CHEST CT FOR EVAULATION OF CHF	Adverse Event	
25 FEB 2021	SLEEP STUDY	Other	RULE OUT SLEEP APNEA

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:32:31

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

US3742330

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:32:31

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 ☐

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 16:17
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

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/DEC/2020 16:49
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

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/DEC/2020 15:42
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

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 10:10
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

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 18:02:10

Generated On: 10 Jun 2021 09:32:31

SAEID	USA-US127-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/DEC/2020 07:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742330 (Prod: University of Maryland School of Medicine)

US3742330

Form: Participant Creation

Generated On: 10 Jun 2021 09:32:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'US3742330'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:22

US3742330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 15:26:55

US3742330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:23

US3742330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	11 Sep 2020 15:26:55

US3742330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'SCRN'	System	11 Sep 2020 15:26:55

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:24

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '74'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'YEARS'	System	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '74'	System	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Female (F)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'I'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:32:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:28:03

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Sep 2020'	System	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2020'	System	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:24

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 13:44:23

US3742330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:32:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'I'	System	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:32:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 19:42:46

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
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)	11 Sep 2020 19:45:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:45:43
Data point term sent to Coder	System	11 Sep 2020 19:44:49
User entered 'hypertension'	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2005'	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2005'	System	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2005'	System	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:43:56

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 19:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:52:44
Data point term sent to Coder	System	11 Sep 2020 19:52:13
User entered 'hypercholesterolemia'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2010'	Hassan Haji (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2010'	System	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2010'	System	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:51:26

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume increased, PT: Fluid retention, LLT: Fluid retention - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:52:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:52:42
Data point term sent to Coder	System	11 Sep 2020 19:52:14
User entered 'fluid retention'	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2010'	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2010'	System	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2010'	System	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:52:01

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 19:54:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 19:54:47
Data point term sent to Coder	System	11 Sep 2020 19:53:16
User entered 'sinus congestion'	Hassan Haji (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
Signature has been broken.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:32:43
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 17:32:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2017'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2010'	System	06 Apr 2021 17:32:43
User entered 'Jan 2017'	System	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2010'	System	06 Apr 2021 17:32:43
User entered '2017'	System	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:52:30

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Nephrectomy, LLT: Nephrectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 04:49:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:49:48
Data point term sent to Coder	System	11 Sep 2020 19:54:17
User entered 'nephrectomy (R)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2006'	Hassan Haji (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2006'	System	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2006'	System	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:53:23

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal failure, LLT: Renal insufficiency - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 04:06:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 04:06:46
Data point term sent to Coder	System	11 Sep 2020 19:54:18
User entered 'stage 2 renal insufficiency'	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2006'	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2006'	System	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2006'	System	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	11 Sep 2020 19:54:04

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:46:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:46:32
Data point term sent to Coder	System	09 Oct 2020 18:45:35
User entered 'MENOPAUSE'	(b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2000'	System	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2000'	System	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	09 Oct 2020 18:45:24

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
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 18:46:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:46:46
Data point term sent to Coder	System	23 Dec 2020 18:45:28
User entered 'obesity'	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'I'	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Kaitlin Mason (b) (4)	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	23 Dec 2020 18:44:33

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:55:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:55:57
Data point term sent to Coder	System	12 Jan 2021 17:55:28
User entered 'osteoarthritis - bilateral knees'	Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2017'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Sherry McCammon (b) (4)	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'Jan 2017'	System	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '2017'	System	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered empty.	System	12 Jan 2021 17:54:28

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '10:09'	Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '11 Sep 2020 10:09'	System	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '67.0' in	(b) (4)	
	Sherry McCammon (b) (4)	18 Sep 2020 19:33:02
DataPoint set to visible.	(b) (4)	
	System	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '305.0' lb	(b) (4)	
	Sherry McCammon (b) (4)	18 Sep 2020 19:33:02
DataPoint set to visible.	(b) (4)	
	System	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered '47.86964'	System	18 Sep 2020 19:33:02
DataPoint set to visible.	System	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'kg/m2'	System	18 Sep 2020 19:33:02
DataPoint set to visible.	System	11 Sep 2020 15:28:29

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done.	Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'bpm'	System	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'breaths/min'	System	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'mmHg'	System	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User entered 'mmHg'	System	18 Sep 2020 19:33:02

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59

US3742330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59

US3742330

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	18 Sep 2020 19:33:37

US3742330

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Sherry McCammon (b) (4)	18 Sep 2020 19:33:37

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:50:42
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'MENOPAUSE HAS BEEN ADDED TO MEDICAL HISTORY' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 18:45:56
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 04:29:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'UN UNK 2000'	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:32:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:08:15

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'curch volunteer exposure to grandchildren'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'I'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 15:29:52

US3742330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:32:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:59
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 15:29:52

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:08:56

US3742330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 20:08:56

US3742330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	11 Sep 2020 20:08:56

US3742330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'VISIT1'	System	11 Sep 2020 20:08:56

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:50:07

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '190675'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:50:07

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:50:07

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:09:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:09:20

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
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 00:05:19
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 18:43:25
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 19:49:23
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:09:20

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:09:20

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:09:20

US3742330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:04:23
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:07:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:07:33

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:00:39
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:59:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:59:06
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:10:05
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:59:06
User entered '305' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:00:39
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:59:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:59:06
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:10:05
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:59:06
User entered '305' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '10:09'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '11 Sep 2020 10:09'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '098.3' F	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '080'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'bpm'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '16'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'breaths/min'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '114'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '070'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:00:39
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:59:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 15:59:06
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:10:05
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:59:06
User entered '305' lb	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11:58'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '11 Sep 2020 11:58'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '97.8' F	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '066'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'bpm'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '14'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'breaths/min'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '123'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '081'	Hassan Haji (b) (4)	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	11 Sep 2020 20:20:52

US3742330

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	18 Sep 2020 19:29:29
User entered 'Yes (Y)'	(b) (4)	
	Hassan Haji (b) (4)	11 Sep 2020 20:21:02
	(b) (4)	

US3742330

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	18 Sep 2020 19:29:29
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 20:21:02

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11:22'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '11 Sep 2020 11:22'	System	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'ONCE'	System	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:58:41

US3742330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 15:30:23

US3742330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 15:30:23

US3742330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '10:15'	Hassan Haji (b) (4)	11 Sep 2020 15:30:23

US3742330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '11 Sep 2020 10:15'	System	11 Sep 2020 15:30:23

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11 Sep 2020'	Hassan Haji (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '10:13'	Hassan Haji (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '11 Sep 2020 10:13'	System	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	11 Sep 2020 15:30:41

US3742330

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:22:14

US3742330

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '1'	System	11 Sep 2020 20:22:14

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:07:51', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2f949210-a8d7-49d6-89e7-2db9369917c6' User entered 'Yes (Y)'	System	11 Sep 2020 16:09:07
	System	11 Sep 2020 16:09:07

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:08:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2f949210-a8d7-49d6-89e7-2db9369917c6' User entered '97.8'	System	11 Sep 2020 16:09:07
	System	11 Sep 2020 16:09:07

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:08:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2f949210-a8d7-49d6-89e7-2db9369917c6' User entered 'No (N)'	System	11 Sep 2020 16:09:07
	System	11 Sep 2020 16:09:07

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:08:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2f949210-a8d7-49d6-89e7-2db9369917c6' User entered '11 Sep 2020 12:08'	System	11 Sep 2020 16:09:07
	System	11 Sep 2020 16:09:07

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 11:42'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:04:59', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc131b7d-4043-4b2e-815c-2be03a049215' User entered 'Yes (Y)'	System	12 Sep 2020 02:12:06
	System	12 Sep 2020 02:12:06

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:11:47', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc131b7d-4043-4b2e-815c-2be03a049215' User entered '97.6'	System	12 Sep 2020 02:12:06
	System	12 Sep 2020 02:12:06

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:11:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc131b7d-4043-4b2e-815c-2be03a049215' User entered 'No (N)'	System	12 Sep 2020 02:12:06
	System	12 Sep 2020 02:12:06

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:12:03', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc131b7d-4043-4b2e-815c-2be03a049215' User entered '11 Sep 2020 22:12'	System	12 Sep 2020 02:12:06
	System	12 Sep 2020 02:12:06

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 2'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:01:08', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8502105b-2623-4df3-8e82-9da35b3d4994'	System	13 Sep 2020 02:03:10
User entered 'Yes (Y)'	System	13 Sep 2020 02:03:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:02:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8502105b-2623-4df3-8e82-9da35b3d4994' User entered '96.8'	System	13 Sep 2020 02:03:10
	System	13 Sep 2020 02:03:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:02:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8502105b-2623-4df3-8e82-9da35b3d4994'	System	13 Sep 2020 02:03:10
User entered 'No (N)'	System	13 Sep 2020 02:03:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8502105b-2623-4df3-8e82-9da35b3d4994'	System	13 Sep 2020 02:03:10
User entered '12 Sep 2020 22:03'	System	13 Sep 2020 02:03:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 3'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:29:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b7fc2f15-287d-4f58-a1d8-adc187f34b92'	System	14 Sep 2020 02:30:46
User entered 'Yes (Y)'	System	14 Sep 2020 02:30:46

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:27', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b7fc2f15-287d-4f58-a1d8-adc187f34b92'	System	14 Sep 2020 02:30:46
User entered '97.8'	System	14 Sep 2020 02:30:46

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b7fc2f15-287d-4f58-a1d8-adc187f34b92'	System	14 Sep 2020 02:30:46
User entered 'No (N)'	System	14 Sep 2020 02:30:46

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b7fc2f15-287d-4f58-a1d8-adc187f34b92'	System	14 Sep 2020 02:30:46
User entered '13 Sep 2020 22:30'	System	14 Sep 2020 02:30:46

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 4'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:40:08', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '26d2e597-824b-4e46-954a-754c1c611c07'	System	15 Sep 2020 02:43:38
User entered 'Yes (Y)'	System	15 Sep 2020 02:43:38

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '26d2e597-824b-4e46-954a-754c1c611c07' User entered '95.8'	System	15 Sep 2020 02:43:38
	System	15 Sep 2020 02:43:38

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '26d2e597-824b-4e46-954a-754c1c611c07'	System	15 Sep 2020 02:43:38
User entered 'No (N)'	System	15 Sep 2020 02:43:38

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:35', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '26d2e597-824b-4e46-954a-754c1c611c07' User entered '14 Sep 2020 22:43'	System	15 Sep 2020 02:43:38
	System	15 Sep 2020 02:43:38

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 5'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:00:46', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2851c2cd-0504-4fd8-b716-ba3c0ff716bc' User entered 'Yes (Y)'	System	16 Sep 2020 02:02:48
	System	16 Sep 2020 02:02:48

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:02:30', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2851c2cd-0504-4fd8-b716-ba3c0ff716bc' User entered '97.9'	System	16 Sep 2020 02:02:48
	System	16 Sep 2020 02:02:48

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:02:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2851c2cd-0504-4fd8-b716-ba3c0ff716bc' User entered 'No (N)'	System	16 Sep 2020 02:02:48
	System	16 Sep 2020 02:02:48

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:02:44', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '2851c2cd-0504-4fd8-b716-ba3c0ff716bc' User entered '15 Sep 2020 22:02'	System	16 Sep 2020 02:02:48
	System	16 Sep 2020 02:02:48

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 6'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:51:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9a6a820c-62d4-4438-8ca7-757beb41790c' User entered 'Yes (Y)'	System	17 Sep 2020 12:52:16
	System	17 Sep 2020 12:52:16

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:51:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9a6a820c-62d4-4438-8ca7-757beb41790c' User entered '96.2'	System	17 Sep 2020 12:52:16
	System	17 Sep 2020 12:52:16

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:51:59', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9a6a820c-62d4-4438-8ca7-757beb41790c' User entered 'No (N)'	System	17 Sep 2020 12:52:16
	System	17 Sep 2020 12:52:16

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9a6a820c-62d4-4438-8ca7-757beb41790c' User entered '17 Sep 2020 08:52'	System	17 Sep 2020 12:52:16
	System	17 Sep 2020 12:52:16

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 7'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:00:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd61277f3-deb7-43c1-a3e8-f9a509bc48fb' User entered 'Yes (Y)'	System	18 Sep 2020 02:02:10
	System	18 Sep 2020 02:02:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:01:46', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd61277f3-deb7-43c1-a3e8-f9a509bc48fb' User entered '97.6'	System	18 Sep 2020 02:02:10
	System	18 Sep 2020 02:02:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:01:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd61277f3-deb7-43c1-a3e8-f9a509bc48fb' User entered 'No (N)'	System	18 Sep 2020 02:02:10
	System	18 Sep 2020 02:02:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:01:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd61277f3-deb7-43c1-a3e8-f9a509bc48fb' User entered '17 Sep 2020 22:01'	System	18 Sep 2020 02:02:10
	System	18 Sep 2020 02:02:10

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'bb9fc7ae-aa5b-4d0e-b934-4115da7aea55'	System	11 Sep 2020 16:09:26
User entered 'None (1)'	System	11 Sep 2020 16:09:26

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'bb9fc7ae-aa5b-4d0e-b934-4115da7aea55'	System	11 Sep 2020 16:09:26
User entered 'No (N)'	System	11 Sep 2020 16:09:26

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'bb9fc7ae-aa5b-4d0e-b934-4115da7aea55' User entered 'No (N)'	System	11 Sep 2020 16:09:26
	System	11 Sep 2020 16:09:26

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:16', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'bb9fc7ae-aa5b-4d0e-b934-4115da7aea55'	System	11 Sep 2020 16:09:26
User entered 'None (1)'	System	11 Sep 2020 16:09:26

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'bb9fc7ae-aa5b-4d0e-b934-4115da7aea55'	System	11 Sep 2020 16:09:26
User entered '11 Sep 2020 12:09'	System	11 Sep 2020 16:09:26

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 11:42'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:12:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e79e6d68-d1a8-43a9-95c9-dab898cfa8e1' User entered 'None (1)'	System	12 Sep 2020 02:13:06
	System	12 Sep 2020 02:13:06

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:12:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e79e6d68-d1a8-43a9-95c9-dab898cfa8e1' User entered 'No (N)'	System	12 Sep 2020 02:13:06
	System	12 Sep 2020 02:13:06

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:12:39', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e79e6d68-d1a8-43a9-95c9-dab898cfa8e1' User entered 'No (N)'	System	12 Sep 2020 02:13:06
	System	12 Sep 2020 02:13:06

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:12:47', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e79e6d68-d1a8-43a9-95c9-dab898cfa8e1' User entered 'None (1)'	System	12 Sep 2020 02:13:06
	System	12 Sep 2020 02:13:06

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e79e6d68-d1a8-43a9-95c9-dab898cfa8e1' User entered '11 Sep 2020 22:13'	System	12 Sep 2020 02:13:06
	System	12 Sep 2020 02:13:06

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 2'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '77048a69-518f-4792-a5bb-bd7eabb6ed0d' User entered 'None (1)'	System	13 Sep 2020 02:03:56
	System	13 Sep 2020 02:03:56

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '77048a69-518f-4792-a5bb-bd7eabb6ed0d' User entered 'No (N)'	System	13 Sep 2020 02:03:56
	System	13 Sep 2020 02:03:56

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:35', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '77048a69-518f-4792-a5bb-bd7eabb6ed0d' User entered 'No (N)'	System	13 Sep 2020 02:03:56
	System	13 Sep 2020 02:03:56

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:44', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '77048a69-518f-4792-a5bb-bd7eabb6ed0d' User entered 'None (1)'	System	13 Sep 2020 02:03:56
	System	13 Sep 2020 02:03:56

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:54', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '77048a69-518f-4792-a5bb-bd7eabb6ed0d' User entered '12 Sep 2020 22:03'	System	13 Sep 2020 02:03:56
	System	13 Sep 2020 02:03:56

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 3'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:50', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b7aeeb5-aec1-4a39-882a-cc5ab8695b0d' User entered 'None (1)'	System	14 Sep 2020 02:31:08
	System	14 Sep 2020 02:31:08

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:54', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b7aeeb5-aec1-4a39-882a-cc5ab8695b0d' User entered 'No (N)'	System	14 Sep 2020 02:31:08
	System	14 Sep 2020 02:31:08

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:30:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b7aeeb5-aec1-4a39-882a-cc5ab8695b0d' User entered 'No (N)'	System	14 Sep 2020 02:31:08
	System	14 Sep 2020 02:31:08

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b7aeeb5-aec1-4a39-882a-cc5ab8695b0d' User entered 'None (1)'	System	14 Sep 2020 02:31:08
	System	14 Sep 2020 02:31:08

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b7aeeb5-aec1-4a39-882a-cc5ab8695b0d' User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:08
	System	14 Sep 2020 02:31:08

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 4'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:41', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '471f87eb-6a05-4ad5-ae87-eeed157c6492'	System	15 Sep 2020 02:44:10
User entered 'None (1)'	System	15 Sep 2020 02:44:10

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '471f87eb-6a05-4ad5-ae87-eeed157c6492'	System	15 Sep 2020 02:44:10
User entered 'No (N)'	System	15 Sep 2020 02:44:10

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:52', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '471f87eb-6a05-4ad5-ae87-eeed157c6492'	System	15 Sep 2020 02:44:10
User entered 'No (N)'	System	15 Sep 2020 02:44:10

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:43:59', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '471f87eb-6a05-4ad5-ae87-eeed157c6492' User entered 'None (1)'	System	15 Sep 2020 02:44:10
	System	15 Sep 2020 02:44:10

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '471f87eb-6a05-4ad5-ae87-eeed157c6492'	System	15 Sep 2020 02:44:10
User entered '14 Sep 2020 22:44'	System	15 Sep 2020 02:44:10

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 5'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:02:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '123649da-e9cb-4f00-9d08-24a1179ba9aa' User entered 'None (1)'	System	16 Sep 2020 02:03:27
	System	16 Sep 2020 02:03:27

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '123649da-e9cb-4f00-9d08-24a1179ba9aa' User entered 'No (N)'	System	16 Sep 2020 02:03:27
	System	16 Sep 2020 02:03:27

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:08', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '123649da-e9cb-4f00-9d08-24a1179ba9aa' User entered 'No (N)'	System	16 Sep 2020 02:03:27
	System	16 Sep 2020 02:03:27

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:13', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '123649da-e9cb-4f00-9d08-24a1179ba9aa'	System	16 Sep 2020 02:03:27
User entered 'None (1)'	System	16 Sep 2020 02:03:27

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '123649da-e9cb-4f00-9d08-24a1179ba9aa' User entered '15 Sep 2020 22:03'	System	16 Sep 2020 02:03:27
	System	16 Sep 2020 02:03:27

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 6'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a982e784-7a63-4ade-8139-d275550a2730' User entered 'None (1)'	System	17 Sep 2020 12:52:37
	System	17 Sep 2020 12:52:37

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a982e784-7a63-4ade-8139-d275550a2730' User entered 'No (N)'	System	17 Sep 2020 12:52:37
	System	17 Sep 2020 12:52:37

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a982e784-7a63-4ade-8139-d275550a2730' User entered 'No (N)'	System	17 Sep 2020 12:52:37
	System	17 Sep 2020 12:52:37

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a982e784-7a63-4ade-8139-d275550a2730' User entered 'None (1)'	System	17 Sep 2020 12:52:37
	System	17 Sep 2020 12:52:37

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a982e784-7a63-4ade-8139-d275550a2730' User entered '17 Sep 2020 08:52'	System	17 Sep 2020 12:52:37
	System	17 Sep 2020 12:52:37

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 7'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '202d79e9-c8f5-4c04-b770-6467f0c6d1d0'	System	18 Sep 2020 02:02:22
User entered 'None (1)'	System	18 Sep 2020 02:02:22

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '202d79e9-c8f5-4c04-b770-6467f0c6d1d0' User entered 'No (N)'	System	18 Sep 2020 02:02:22
	System	18 Sep 2020 02:02:22

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '202d79e9-c8f5-4c04-b770-6467f0c6d1d0' User entered 'No (N)'	System	18 Sep 2020 02:02:22
	System	18 Sep 2020 02:02:22

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:07', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '202d79e9-c8f5-4c04-b770-6467f0c6d1d0'	System	18 Sep 2020 02:02:22
User entered 'None (1)'	System	18 Sep 2020 02:02:22

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '202d79e9-c8f5-4c04-b770-6467f0c6d1d0' User entered '17 Sep 2020 22:02'	System	18 Sep 2020 02:02:22
	System	18 Sep 2020 02:02:22

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:31', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:40', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:43', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'None (0)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:46', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered 'No (N)'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T12:09:50', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '19e36f19-f357-43f5-8573-bd3772dc03da' User entered '11 Sep 2020 12:09'	System	11 Sep 2020 16:09:52
	System	11 Sep 2020 16:09:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 11:42'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 14:12'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:20', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'None (0)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered 'No (N)'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-11T22:13:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c18f39e6-7e7e-466c-9d62-27c97b6ca5fc' User entered '11 Sep 2020 22:13'	System	12 Sep 2020 02:13:37
	System	12 Sep 2020 02:13:37

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 2'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:03:59', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:07', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:13', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'None (0)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered 'No (N)'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-12T22:04:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8733b017-f636-458f-94e6-e0909c334259' User entered '12 Sep 2020 22:04'	System	13 Sep 2020 02:04:25
	System	13 Sep 2020 02:04:25

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 3'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:11', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:16', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'None (0)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered 'No (N)'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-13T22:31:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '253b59cc-c171-4ecf-a21f-bb499f013c98' User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:35
	System	14 Sep 2020 02:31:35

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 4'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:11', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6' User entered 'None (0)'	System	15 Sep 2020 02:44:38
	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6'	System	15 Sep 2020 02:44:38
User entered 'None (0)'	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:16', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6' User entered 'None (0)'	System	15 Sep 2020 02:44:38
	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6' User entered 'None (0)'	System	15 Sep 2020 02:44:38
	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6' User entered 'None (0)'	System	15 Sep 2020 02:44:38
	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6' User entered 'None (0)'	System	15 Sep 2020 02:44:38
	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6'	System	15 Sep 2020 02:44:38
User entered 'No (N)'	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-14T22:44:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b1258fa2-2934-4cc7-ae51-8fba51954b6'	System	15 Sep 2020 02:44:38
User entered '14 Sep 2020 22:44'	System	15 Sep 2020 02:44:38

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 5'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:27', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:30', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:39', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'None (0)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:42', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered 'No (N)'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-15T22:03:46', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '006d68cb-e44c-435b-ae9d-da40f7fc8c06' User entered '15 Sep 2020 22:03'	System	16 Sep 2020 02:03:52
	System	16 Sep 2020 02:03:52

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 6'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:40', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:43', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:47', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'None (0)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:52', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered 'No (N)'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T08:52:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '716c71bc-e7e1-4216-848a-d0c18594f076' User entered '17 Sep 2020 08:52'	System	17 Sep 2020 12:52:58
	System	17 Sep 2020 12:52:58

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 7'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398' User entered 'None (0)'	System	18 Sep 2020 02:02:50
	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:17', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398'	System	18 Sep 2020 02:02:50
User entered 'None (0)'	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398'	System	18 Sep 2020 02:02:50
User entered 'None (0)'	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398' User entered 'None (0)'	System	18 Sep 2020 02:02:50
	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398' User entered 'None (0)'	System	18 Sep 2020 02:02:50
	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:26', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398' User entered 'None (0)'	System	18 Sep 2020 02:02:50
	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398'	System	18 Sep 2020 02:02:50
User entered 'No (N)'	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-09-17T22:02:42', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5fee92e6-594d-4f2a-91ab-ee16b247a398' User entered '17 Sep 2020 22:02'	System	18 Sep 2020 02:02:50
	System	18 Sep 2020 02:02:50

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:58:41

US3742330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:56
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:31:13
User entered 'Yes (Y)'	System	18 Sep 2020 19:30:33
	Sherry McCammon (b) (4)	18 Sep 2020 19:30:33
	(b) (4)	

US3742330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '18 Sep 2020'	Sherry McCammon (b) (4)	18 Sep 2020 19:30:33

US3742330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Sherry McCammon (b) (4)	18 Sep 2020 19:31:13
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	18 Sep 2020 19:30:33
	(b) (4)	

US3742330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	18 Sep 2020 19:30:33

US3742330

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	18 Sep 2020 19:30:39

US3742330

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	18 Sep 2020 19:30:39

US3742330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:18

US3742330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:18

US3742330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:18

US3742330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:18

US3742330

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:22

US3742330

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	28 Sep 2020 14:13:22

US3742330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	02 Oct 2020 19:04:48

US3742330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '02 Oct 2020'	Kaitlin Mason (b) (4)	02 Oct 2020 19:04:48

US3742330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	02 Oct 2020 19:04:48

US3742330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	02 Oct 2020 19:04:48

US3742330

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	02 Oct 2020 19:04:58

US3742330

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	02 Oct 2020 19:04:58

US3742330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:37

US3742330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:37

US3742330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:37

US3742330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'VISIT2'	System	09 Oct 2020 18:46:37

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11:30'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '9 Oct 2020 11:30'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '098.2' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '060'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'bpm'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'breaths/min'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '144'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '079'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '12:55'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '9 Oct 2020 12:55'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '097.5' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '059'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'bpm'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'breaths/min'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '126'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '066'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'mmHg'	System	09 Oct 2020 18:50:33

US3742330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:36

US3742330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:36

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '12:23'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '9 Oct 2020 12:23'	System	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'ONCE'	System	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 16:31:29

US3742330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:50

US3742330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:50

US3742330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11:38'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:46:50

US3742330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '9 Oct 2020 11:38'	System	09 Oct 2020 18:46:50

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:32:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is 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)	09 Nov 2020 01:55:53
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is 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 14:08:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020is 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 11:19:53
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '11:37'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '9 Oct 2020 11:37'	System	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	09 Oct 2020 18:47:04

US3742330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:50:42

US3742330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	09 Oct 2020 18:50:42

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:28:59', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a51cfef6-3bd0-433c-a43b-2bc7b9a278d8' User entered 'Yes (Y)'	System	09 Oct 2020 17:29:20
	System	09 Oct 2020 17:29:20

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:09', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a51cfef6-3bd0-433c-a43b-2bc7b9a278d8' User entered '97.5'	System	09 Oct 2020 17:29:20
	System	09 Oct 2020 17:29:20

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a51cfef6-3bd0-433c-a43b-2bc7b9a278d8'	System	09 Oct 2020 17:29:20
User entered 'No (N)'	System	09 Oct 2020 17:29:20

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a51cfef6-3bd0-433c-a43b-2bc7b9a278d8' User entered '09 Oct 2020 13:29'	System	09 Oct 2020 17:29:20
	System	09 Oct 2020 17:29:20

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 12:43'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 15:13'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:19:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd2cf2a90-7664-447d-bd48-ee45102e7f24' User entered 'Yes (Y)'	System	10 Oct 2020 13:20:28
	System	10 Oct 2020 13:20:28

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:19:56', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd2cf2a90-7664-447d-bd48-ee45102e7f24' User entered '97.6'	System	10 Oct 2020 13:20:28
	System	10 Oct 2020 13:20:28

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:01', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd2cf2a90-7664-447d-bd48-ee45102e7f24'	System	10 Oct 2020 13:20:28
User entered 'No (N)'	System	10 Oct 2020 13:20:28

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:07', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd2cf2a90-7664-447d-bd48-ee45102e7f24' User entered '10 Oct 2020 09:20'	System	10 Oct 2020 13:20:28
	System	10 Oct 2020 13:20:28

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 16:08'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '38a86a26-f982-4a53-9a8c-fecccd05d609' User entered 'Yes (Y)'	System	11 Oct 2020 02:27:38
	System	11 Oct 2020 02:27:38

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:28', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '38a86a26-f982-4a53-9a8c-fecccd05d609' User entered '98.1'	System	11 Oct 2020 02:27:38
	System	11 Oct 2020 02:27:38

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '38a86a26-f982-4a53-9a8c-fecccd05d609' User entered 'No (N)'	System	11 Oct 2020 02:27:38
	System	11 Oct 2020 02:27:38

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '38a86a26-f982-4a53-9a8c-fecccd05d609' User entered '10 Oct 2020 22:27'	System	11 Oct 2020 02:27:38
	System	11 Oct 2020 02:27:38

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:42:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1d88f979-6698-4d83-919f-e3ebaf0b2bb5' User entered 'Yes (Y)'	System	12 Oct 2020 02:43:18
	System	12 Oct 2020 02:43:18

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1d88f979-6698-4d83-919f-e3ebaf0b2bb5' User entered '97.1'	System	12 Oct 2020 02:43:18
	System	12 Oct 2020 02:43:18

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:09', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1d88f979-6698-4d83-919f-e3ebaf0b2bb5'	System	12 Oct 2020 02:43:18
User entered 'No (N)'	System	12 Oct 2020 02:43:18

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1d88f979-6698-4d83-919f-e3ebaf0b2bb5' User entered '11 Oct 2020 22:43'	System	12 Oct 2020 02:43:18
	System	12 Oct 2020 02:43:18

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:32:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0898ef2d-51d7-4a72-9c1b-b00e9b3f3574' User entered 'Yes (Y)'	System	13 Oct 2020 02:34:05
	System	13 Oct 2020 02:34:05

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:33:44', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0898ef2d-51d7-4a72-9c1b-b00e9b3f3574' User entered '96.0'	System	13 Oct 2020 02:34:05
	System	13 Oct 2020 02:34:05

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:33:58', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0898ef2d-51d7-4a72-9c1b-b00e9b3f3574' User entered 'No (N)'	System	13 Oct 2020 02:34:05
	System	13 Oct 2020 02:34:05

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0898ef2d-51d7-4a72-9c1b-b00e9b3f3574' User entered '12 Oct 2020 22:34'	System	13 Oct 2020 02:34:05
	System	13 Oct 2020 02:34:05

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:19:58', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b119123e-0860-40c8-b77b-55628f989757'	System	14 Oct 2020 03:21:47
User entered 'Yes (Y)'	System	14 Oct 2020 03:21:47

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b119123e-0860-40c8-b77b-55628f989757'	System	14 Oct 2020 03:21:47
User entered '96.6'	System	14 Oct 2020 03:21:47

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:37', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b119123e-0860-40c8-b77b-55628f989757'	System	14 Oct 2020 03:21:47
User entered 'No (N)'	System	14 Oct 2020 03:21:47

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:43', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b119123e-0860-40c8-b77b-55628f989757' User entered '13 Oct 2020 23:21'	System	14 Oct 2020 03:21:47
	System	14 Oct 2020 03:21:47

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:03:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '7cd931bb-5db8-4a02-96e9-88bc37f6ab13' User entered 'Yes (Y)'	System	15 Oct 2020 02:05:21
	System	15 Oct 2020 02:05:21

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '7cd931bb-5db8-4a02-96e9-88bc37f6ab13' User entered '97.1'	System	15 Oct 2020 02:05:21
	System	15 Oct 2020 02:05:21

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '7cd931bb-5db8-4a02-96e9-88bc37f6ab13' User entered 'No (N)'	System	15 Oct 2020 02:05:21
	System	15 Oct 2020 02:05:21

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:17', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '7cd931bb-5db8-4a02-96e9-88bc37f6ab13' User entered '14 Oct 2020 22:05'	System	15 Oct 2020 02:05:21
	System	15 Oct 2020 02:05:21

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:02:41', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '67272b1f-e688-4d26-a32c-3cf7c21b0f73' User entered 'Yes (Y)'	System	16 Oct 2020 02:04:13
	System	16 Oct 2020 02:04:13

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '67272b1f-e688-4d26-a32c-3cf7c21b0f73' User entered '96.9'	System	16 Oct 2020 02:04:13
	System	16 Oct 2020 02:04:13

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:03', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '67272b1f-e688-4d26-a32c-3cf7c21b0f73'	System	16 Oct 2020 02:04:13
User entered 'No (N)'	System	16 Oct 2020 02:04:13

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '67272b1f-e688-4d26-a32c-3cf7c21b0f73' User entered '15 Oct 2020 22:04'	System	16 Oct 2020 02:04:13
	System	16 Oct 2020 02:04:13

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '85ab874a-c571-41ad-8db5-fc8dfec19c10'	System	09 Oct 2020 17:29:56
User entered 'None (1)'	System	09 Oct 2020 17:29:56

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '85ab874a-c571-41ad-8db5-fc8dfec19c10' User entered 'No (N)'	System	09 Oct 2020 17:29:56
	System	09 Oct 2020 17:29:56

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '85ab874a-c571-41ad-8db5-fc8dfec19c10' User entered 'No (N)'	System	09 Oct 2020 17:29:56
	System	09 Oct 2020 17:29:56

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:48', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '85ab874a-c571-41ad-8db5-fc8dfec19c10'	System	09 Oct 2020 17:29:56
User entered 'None (1)'	System	09 Oct 2020 17:29:56

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:53', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '85ab874a-c571-41ad-8db5-fc8dfec19c10' User entered '09 Oct 2020 13:29'	System	09 Oct 2020 17:29:56
	System	09 Oct 2020 17:29:56

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 12:43'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 15:13'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:11', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd31c5da9-71ac-45ca-ab13-7f211b38d5ef' User entered 'None (1)'	System	10 Oct 2020 13:20:29
	System	10 Oct 2020 13:20:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd31c5da9-71ac-45ca-ab13-7f211b38d5ef' User entered 'No (N)'	System	10 Oct 2020 13:20:29
	System	10 Oct 2020 13:20:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:17', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd31c5da9-71ac-45ca-ab13-7f211b38d5ef' User entered 'No (N)'	System	10 Oct 2020 13:20:29
	System	10 Oct 2020 13:20:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:20', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd31c5da9-71ac-45ca-ab13-7f211b38d5ef' User entered 'None (1)'	System	10 Oct 2020 13:20:29
	System	10 Oct 2020 13:20:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd31c5da9-71ac-45ca-ab13-7f211b38d5ef' User entered '10 Oct 2020 09:20'	System	10 Oct 2020 13:20:29
	System	10 Oct 2020 13:20:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 16:08'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'edfccf2d-17b2-4b77-9ed4-6d8aa4276344' User entered 'None (1)'	System	11 Oct 2020 02:28:10
	System	11 Oct 2020 02:28:10

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:27:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'edfccf2d-17b2-4b77-9ed4-6d8aa4276344' User entered 'No (N)'	System	11 Oct 2020 02:28:10
	System	11 Oct 2020 02:28:10

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'edfccf2d-17b2-4b77-9ed4-6d8aa4276344' User entered 'No (N)'	System	11 Oct 2020 02:28:10
	System	11 Oct 2020 02:28:10

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'edfccf2d-17b2-4b77-9ed4-6d8aa4276344' User entered 'None (1)'	System	11 Oct 2020 02:28:10
	System	11 Oct 2020 02:28:10

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:09', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'edfccf2d-17b2-4b77-9ed4-6d8aa4276344' User entered '10 Oct 2020 22:28'	System	11 Oct 2020 02:28:10
	System	11 Oct 2020 02:28:10

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'af27b83d-fd07-4f39-aeed-7c338a36b4ed'	System	12 Oct 2020 02:45:14
User entered 'None (1)'	System	12 Oct 2020 02:45:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'af27b83d-fd07-4f39-aeed-7c338a36b4ed' User entered 'No (N)'	System	12 Oct 2020 02:45:14
	System	12 Oct 2020 02:45:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'af27b83d-fd07-4f39-aeed-7c338a36b4ed' User entered 'No (N)'	System	12 Oct 2020 02:45:14
	System	12 Oct 2020 02:45:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:43:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'af27b83d-fd07-4f39-aeed-7c338a36b4ed'	System	12 Oct 2020 02:45:14
User entered 'None (1)'	System	12 Oct 2020 02:45:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'af27b83d-fd07-4f39-aeed-7c338a36b4ed' User entered '11 Oct 2020 22:45'	System	12 Oct 2020 02:45:14
	System	12 Oct 2020 02:45:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:06', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '94f38e2b-fde7-4409-8c20-ff2b083928da'	System	13 Oct 2020 02:34:21
User entered 'None (1)'	System	13 Oct 2020 02:34:21

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '94f38e2b-fde7-4409-8c20-ff2b083928da' User entered 'No (N)'	System	13 Oct 2020 02:34:21
	System	13 Oct 2020 02:34:21

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '94f38e2b-fde7-4409-8c20-ff2b083928da'	System	13 Oct 2020 02:34:21
User entered 'No (N)'	System	13 Oct 2020 02:34:21

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '94f38e2b-fde7-4409-8c20-ff2b083928da' User entered 'None (1)'	System	13 Oct 2020 02:34:21
	System	13 Oct 2020 02:34:21

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '94f38e2b-fde7-4409-8c20-ff2b083928da' User entered '12 Oct 2020 22:34'	System	13 Oct 2020 02:34:21
	System	13 Oct 2020 02:34:21

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:47', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1396bf6f-730e-4e69-94bd-bdcccde167c80'	System	14 Oct 2020 03:22:14
User entered 'None (1)'	System	14 Oct 2020 03:22:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:51', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1396bf6f-730e-4e69-94bd-bdccde167c80' User entered 'No (N)'	System	14 Oct 2020 03:22:14
	System	14 Oct 2020 03:22:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:54', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1396bf6f-730e-4e69-94bd-bdccde167c80' User entered 'No (N)'	System	14 Oct 2020 03:22:14
	System	14 Oct 2020 03:22:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:21:56', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1396bf6f-730e-4e69-94bd-bdcccde167c80' User entered 'None (1)'	System	14 Oct 2020 03:22:14
	System	14 Oct 2020 03:22:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:09', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '1396bf6f-730e-4e69-94bd-bdccde167c80' User entered '13 Oct 2020 23:22'	System	14 Oct 2020 03:22:14
	System	14 Oct 2020 03:22:14

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5190d1cd-eb5c-4093-8987-30eae8cbe6a0' User entered 'None (1)'	System	15 Oct 2020 02:05:36
	System	15 Oct 2020 02:05:36

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5190d1cd-eb5c-4093-8987-30eae8cbe6a0' User entered 'No (N)'	System	15 Oct 2020 02:05:36
	System	15 Oct 2020 02:05:36

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:28', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5190d1cd-eb5c-4093-8987-30eae8cbe6a0' User entered 'No (N)'	System	15 Oct 2020 02:05:36
	System	15 Oct 2020 02:05:36

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:31', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5190d1cd-eb5c-4093-8987-30eae8cbe6a0' User entered 'None (1)'	System	15 Oct 2020 02:05:36
	System	15 Oct 2020 02:05:36

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:33', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5190d1cd-eb5c-4093-8987-30eae8cbe6a0' User entered '14 Oct 2020 22:05'	System	15 Oct 2020 02:05:36
	System	15 Oct 2020 02:05:36

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd65452a9-b383-4a2f-89a7-7b22fe5eed74' User entered 'None (1)'	System	16 Oct 2020 02:04:29
	System	16 Oct 2020 02:04:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd65452a9-b383-4a2f-89a7-7b22fe5eed74' User entered 'No (N)'	System	16 Oct 2020 02:04:29
	System	16 Oct 2020 02:04:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:20', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd65452a9-b383-4a2f-89a7-7b22fe5eed74' User entered 'No (N)'	System	16 Oct 2020 02:04:29
	System	16 Oct 2020 02:04:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd65452a9-b383-4a2f-89a7-7b22fe5eed74' User entered 'None (1)'	System	16 Oct 2020 02:04:29
	System	16 Oct 2020 02:04:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:26', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd65452a9-b383-4a2f-89a7-7b22fe5eed74' User entered '15 Oct 2020 22:04'	System	16 Oct 2020 02:04:29
	System	16 Oct 2020 02:04:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:29:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:02', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:08', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'None (0)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered 'No (N)'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-09T13:30:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'c2488ab4-d2eb-4074-bca2-ddeb18092391' User entered '09 Oct 2020 13:30'	System	09 Oct 2020 17:30:28
	System	09 Oct 2020 17:30:28

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 12:43'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 15:13'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:37', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:39', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:41', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'None (0)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:46', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered 'No (N)'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T09:20:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '030606de-1d41-4fc4-a863-a85c811881f1' User entered '10 Oct 2020 09:20'	System	10 Oct 2020 13:20:52
	System	10 Oct 2020 13:20:52

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '09 Oct 2020 16:08'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 2'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:12', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:17', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:21', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'None (0)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:26', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered 'No (N)'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-10T22:28:28', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '575f0e2d-0ba4-436b-8801-3e98070d3929' User entered '10 Oct 2020 22:28'	System	11 Oct 2020 02:28:31
	System	11 Oct 2020 02:28:31

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 3'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:16', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:24', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:26', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'None (0)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered 'No (N)'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-11T22:45:33', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '0b98344b-7023-48fe-9406-3360e403943e' User entered '11 Oct 2020 22:45'	System	12 Oct 2020 02:45:38
	System	12 Oct 2020 02:45:38

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 4'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:23', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:27', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:31', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:33', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'None (0)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered 'No (N)'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-12T22:34:42', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '5be83789-54c8-4320-b83e-64df82f3b761' User entered '12 Oct 2020 22:34'	System	13 Oct 2020 02:34:44
	System	13 Oct 2020 02:34:44

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 5'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:13', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:20', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'None (0)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:28', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered 'No (N)'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-13T23:22:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '58327f8b-2847-43d3-998f-6124f5c8b370' User entered '13 Oct 2020 23:22'	System	14 Oct 2020 03:22:37
	System	14 Oct 2020 03:22:37

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 6'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:40', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:42', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:44', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:48', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:50', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'None (0)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:52', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered 'No (N)'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-14T22:05:55', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'f97dc83e-c820-4b68-90b5-c8c7800476f3' User entered '14 Oct 2020 22:05'	System	15 Oct 2020 02:05:59
	System	15 Oct 2020 02:05:59

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	09 Oct 2020 16:31:29
User entered 'Day 7'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:30', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:41', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered 'None (0)'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:49', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7'	System	16 Oct 2020 02:05:01
User entered 'No (N)'	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-10-15T22:04:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'd81ff4a1-54d2-41e6-9a9a-b8959e9b98f7' User entered '15 Oct 2020 22:04'	System	16 Oct 2020 02:05:01
	System	16 Oct 2020 02:05:01

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:31:29

US3742330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:32:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:31:29

US3742330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:34:13

US3742330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '16 Oct 2020'	Kaitlin Mason (b) (4)	20 Oct 2020 20:34:13

US3742330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:34:13

US3742330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 20:34:13

US3742330

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	20 Oct 2020 20:34:19

US3742330

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	20 Oct 2020 20:34:19

US3742330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 19:30:22

US3742330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 19:30:22

US3742330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	23 Oct 2020 19:30:22

US3742330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:30:22

US3742330

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 19:30:26

US3742330

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	23 Oct 2020 19:30:26

US3742330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	30 Oct 2020 15:46:24

US3742330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '30 Oct 2020'	Hassan Haji (b) (4)	30 Oct 2020 15:46:24

US3742330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	30 Oct 2020 15:46:24

US3742330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:46:24

US3742330

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	30 Oct 2020 15:46:29

US3742330

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	30 Oct 2020 15:46:29

US3742330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 16:39:49

US3742330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 16:39:49

US3742330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	06 Nov 2020 16:39:49

US3742330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'VISIT3'	System	06 Nov 2020 16:39:49

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'No (N)'	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered empty.	Hassan Haji (b) (4)	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered empty.	System	06 Nov 2020 16:40:01

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22

US3742330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22

US3742330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 16:40:22

US3742330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 16:40:22

US3742330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 16:48:12

US3742330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '6 Nov 2020'	Hassan Haji (b) (4)	06 Nov 2020 16:48:12

US3742330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered '10:58'	Hassan Haji (b) (4)	06 Nov 2020 16:48:12

US3742330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered '6 Nov 2020 10:58'	System	06 Nov 2020 16:48:12

US3742330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:44:34
User entered 'Yes (Y)'	Hassan Haji (b) (4)	06 Nov 2020 16:49:06

US3742330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	06 Nov 2020 16:49:06

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 64'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-14T13:50:44', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8005ffb1-316b-47b3-a611-5aeeb9ef0621'	System	14 Nov 2020 18:51:37
User entered 'No (N)'	System	14 Nov 2020 18:51:37

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-14T13:51:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8005ffb1-316b-47b3-a611-5aeeb9ef0621'	System	14 Nov 2020 18:51:37
User entered 'No (N)'	System	14 Nov 2020 18:51:37

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-14T13:51:35', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8005ffb1-316b-47b3-a611-5aeeb9ef0621' User entered '14 Nov 2020 13:51:35'	System	14 Nov 2020 18:51:37
	System	14 Nov 2020 18:51:37

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered 'Day 71'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-19T17:47:01', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '18fecf9c-acbb-4fba-bf4f-7e3ebe453fbd'	System	19 Nov 2020 22:47:26
User entered 'No (N)'	System	19 Nov 2020 22:47:26

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-19T17:47:04', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '18fecf9c-acbb-4fba-bf4f-7e3ebe453fbd'	System	19 Nov 2020 22:47:26
User entered 'No (N)'	System	19 Nov 2020 22:47:26

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-19T17:47:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '18fecf9c-acbb-4fba-bf4f-7e3ebe453fbd' User entered '19 Nov 2020 17:47:14'	System	19 Nov 2020 22:47:26
	System	19 Nov 2020 22:47:26

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 15:58:41

US3742330

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:39:59
Data entry locked.	System	11 Sep 2020 15:58:41
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 15:58:41

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-23T10:01:27', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8538ee7f-e9dc-43f4-a2b8-b2f49b397911' User entered 'No (N)'	System	23 Nov 2020 15:01:42

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-23T10:01:31', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8538ee7f-e9dc-43f4-a2b8-b2f49b397911'	System	23 Nov 2020 15:01:42
User entered 'No (N)'	System	23 Nov 2020 15:01:42

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-23T10:01:34', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '8538ee7f-e9dc-43f4-a2b8-b2f49b397911' User entered '23 Nov 2020 10:01:34'	System	23 Nov 2020 15:01:42

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:00:45', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c' User entered 'Yes (Y)'	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:00:52', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c' User entered 'No (N)'	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:00:57', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c' User entered 'No (N)'	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:01:05', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c' User entered 'Yes (Y)'	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:01:11', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c'	System	30 Nov 2020 20:01:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-11-30T15:01:19', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'dedf0fe6-1c05-43e5-a666-16efb5f4572c' User entered '30 Nov 2020 15:01:19'	System	30 Nov 2020 20:01:29
	System	30 Nov 2020 20:01:29

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:18', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557'	System	08 Dec 2020 15:41:51
User entered 'Yes (Y)'	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:22', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557'	System	08 Dec 2020 15:41:51
User entered 'No (N)'	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557'	System	08 Dec 2020 15:41:51
User entered 'No (N)'	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:29', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557'	System	08 Dec 2020 15:41:51
User entered 'Yes (Y)'	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:37', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557'	System	08 Dec 2020 15:41:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-08T10:41:43', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '163613b1-0e2b-4794-8444-10c90baf0557' User entered '08 Dec 2020 10:41:43'	System	08 Dec 2020 15:41:51
	System	08 Dec 2020 15:41:51

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-16T12:04:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9ce1c0dc-c584-48c4-8154-b64ce0ff0380'	System	16 Dec 2020 17:04:30
User entered 'No (N)'	System	16 Dec 2020 17:04:30

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-16T12:04:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9ce1c0dc-c584-48c4-8154-b64ce0ff0380' User entered 'No (N)'	System	16 Dec 2020 17:04:30

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-16T12:04:26', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '9ce1c0dc-c584-48c4-8154-b64ce0ff0380' User entered '16 Dec 2020 12:04:26'	System	16 Dec 2020 17:04:30
	System	16 Dec 2020 17:04:30

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-24T09:42:32', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '17358b9d-da67-4b49-affa-73aa922cb547'	System	24 Dec 2020 14:42:46
User entered 'No (N)'	System	24 Dec 2020 14:42:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-24T09:42:36', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '17358b9d-da67-4b49-affa-73aa922cb547'	System	24 Dec 2020 14:42:46
User entered 'No (N)'	System	24 Dec 2020 14:42:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-24T09:42:41', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '17358b9d-da67-4b49-affa-73aa922cb547'	System	24 Dec 2020 14:42:46
User entered '24 Dec 2020 09:42:41'	System	24 Dec 2020 14:42:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-31T10:18:33', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '037c2fd8-67ff-4364-a2a6-1670713d475a' User entered 'No (N)'	System	31 Dec 2020 15:18:46
	System	31 Dec 2020 15:18:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-31T10:18:38', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '037c2fd8-67ff-4364-a2a6-1670713d475a' User entered 'No (N)'	System	31 Dec 2020 15:18:46
	System	31 Dec 2020 15:18:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2020-12-31T10:18:43', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '037c2fd8-67ff-4364-a2a6-1670713d475a' User entered '31 Dec 2020 10:18:43'	System	31 Dec 2020 15:18:46
	System	31 Dec 2020 15:18:46

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-07T09:27:10', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '6880c105-568d-4684-81f2-e8a7e5a2b44d' User entered 'No (N)'	System	07 Jan 2021 14:27:22
	System	07 Jan 2021 14:27:22

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-07T09:27:15', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '6880c105-568d-4684-81f2-e8a7e5a2b44d' User entered 'No (N)'	System	07 Jan 2021 14:27:22

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-07T09:27:20', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '6880c105-568d-4684-81f2-e8a7e5a2b44d' User entered '07 Jan 2021 09:27:20'	System	07 Jan 2021 14:27:22
	System	07 Jan 2021 14:27:22

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-14T11:50:30', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4d770569-1216-4813-b4b0-783a733c8ffb' User entered 'No (N)'	System	14 Jan 2021 16:50:44
	System	14 Jan 2021 16:50:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-14T11:50:33', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4d770569-1216-4813-b4b0-783a733c8ffb' User entered 'No (N)'	System	14 Jan 2021 16:50:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-14T11:50:40', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4d770569-1216-4813-b4b0-783a733c8ffb' User entered '14 Jan 2021 11:50:40'	System	14 Jan 2021 16:50:44
	System	14 Jan 2021 16:50:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-20T12:03:51', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '40ce7257-7bef-4a97-b7ae-5a41bc294405'	System	20 Jan 2021 17:04:12
User entered 'No (N)'	System	20 Jan 2021 17:04:12

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-20T12:03:54', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '40ce7257-7bef-4a97-b7ae-5a41bc294405'	System	20 Jan 2021 17:04:12
User entered 'No (N)'	System	20 Jan 2021 17:04:12

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-20T12:03:58', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '40ce7257-7bef-4a97-b7ae-5a41bc294405' User entered '20 Jan 2021 12:03:58'	System	20 Jan 2021 17:04:12

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-27T09:18:37', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'df9db9b4-c66f-4d0d-9e1f-ef5fc41fea98'	System	27 Jan 2021 14:18:44
User entered 'No (N)'	System	27 Jan 2021 14:18:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-27T09:18:39', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'df9db9b4-c66f-4d0d-9e1f-ef5fc41fea98'	System	27 Jan 2021 14:18:44
User entered 'No (N)'	System	27 Jan 2021 14:18:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-01-27T09:18:42', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'df9db9b4-c66f-4d0d-9e1f-ef5fc41fea98'	System	27 Jan 2021 14:18:44
User entered '27 Jan 2021 09:18:42'	System	27 Jan 2021 14:18:44

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-03T22:08:07', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '412831f9-20ca-4127-b957-9e28f2bc7ed2' User entered 'No (N)'	System	04 Feb 2021 03:08:19
	System	04 Feb 2021 03:08:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-03T22:08:09', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '412831f9-20ca-4127-b957-9e28f2bc7ed2'	System	04 Feb 2021 03:08:19
User entered 'No (N)'	System	04 Feb 2021 03:08:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-03T22:08:14', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '412831f9-20ca-4127-b957-9e28f2bc7ed2'	System	04 Feb 2021 03:08:19
User entered '03 Feb 2021 22:08:14'	System	04 Feb 2021 03:08:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-17T08:46:25', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4007cea4-a105-4b22-a371-38aa0129ae78' User entered 'No (N)'	System	17 Feb 2021 13:46:40
	System	17 Feb 2021 13:46:40

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-17T08:46:27', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4007cea4-a105-4b22-a371-38aa0129ae78' User entered 'No (N)'	System	17 Feb 2021 13:46:40

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-17T08:46:31', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4007cea4-a105-4b22-a371-38aa0129ae78' User entered '17 Feb 2021 08:46:31'	System	17 Feb 2021 13:46:40
	System	17 Feb 2021 13:46:40

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-25T08:48:55-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e4bcb6bc-de44-4a62-a69d-b1b77a3db286'	System	25 Feb 2021 13:49:05
User entered 'No (N)'	System	25 Feb 2021 13:49:05

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-25T08:48:58-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e4bcb6bc-de44-4a62-a69d-b1b77a3db286'	System	25 Feb 2021 13:49:05
User entered 'No (N)'	System	25 Feb 2021 13:49:05

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-02-25T08:49:03-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'e4bcb6bc-de44-4a62-a69d-b1b77a3db286'	System	25 Feb 2021 13:49:05
User entered '25 Feb 2021 13:49:03'	System	25 Feb 2021 13:49:05

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-02T09:29:45-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '61388e29-d910-4d9a-a969-fcfffdd375dba' User entered 'No (N)'	System	02 Mar 2021 14:29:55
	System	02 Mar 2021 14:29:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-02T09:29:48-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '61388e29-d910-4d9a-a969-fcfffdd375dba'	System	02 Mar 2021 14:29:55
User entered 'No (N)'	System	02 Mar 2021 14:29:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-02T09:29:52-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '61388e29-d910-4d9a-a969-fcffdd375dba' User entered '02 Mar 2021 09:29:52'	System	02 Mar 2021 14:29:55
	System	02 Mar 2021 14:29:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-10T09:04:05-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc972cd4-f972-40f5-b0cf-8d89a662bdf8'	System	10 Mar 2021 14:04:16
User entered 'No (N)'	System	10 Mar 2021 14:04:16

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-10T09:04:08-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc972cd4-f972-40f5-b0cf-8d89a662bdf8'	System	10 Mar 2021 14:04:16
User entered 'No (N)'	System	10 Mar 2021 14:04:16

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-10T09:04:12-05:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'cc972cd4-f972-40f5-b0cf-8d89a662bdf8'	System	10 Mar 2021 14:04:16
User entered '10 Mar 2021 09:04:12'	System	10 Mar 2021 14:04:16

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-18T09:06:11-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b5ca70f9-de12-411b-a2ea-c92681d2c884'	System	18 Mar 2021 13:06:19
User entered 'No (N)'	System	18 Mar 2021 13:06:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-18T09:06:13-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b5ca70f9-de12-411b-a2ea-c92681d2c884'	System	18 Mar 2021 13:06:19
User entered 'No (N)'	System	18 Mar 2021 13:06:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-18T09:06:16-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'b5ca70f9-de12-411b-a2ea-c92681d2c884'	System	18 Mar 2021 13:06:19
User entered '18 Mar 2021 09:06:16'	System	18 Mar 2021 13:06:19

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-25T11:26:59-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a8a2522f-f180-4493-a12a-07d249dd0eb8'	System	25 Mar 2021 15:27:14
User entered 'No (N)'	System	25 Mar 2021 15:27:14

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-25T11:27:01-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a8a2522f-f180-4493-a12a-07d249dd0eb8'	System	25 Mar 2021 15:27:14
User entered 'No (N)'	System	25 Mar 2021 15:27:14

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-25T11:27:07-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'a8a2522f-f180-4493-a12a-07d249dd0eb8' User entered '25 Mar 2021 11:27:07'	System	25 Mar 2021 15:27:14
	System	25 Mar 2021 15:27:14

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-31T09:17:38-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'db5d9885-ea27-4091-8ded-e3976deb3e46'	System	31 Mar 2021 13:17:47
User entered 'No (N)'	System	31 Mar 2021 13:17:47

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-31T09:17:40-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'db5d9885-ea27-4091-8ded-e3976deb3e46'	System	31 Mar 2021 13:17:47
User entered 'No (N)'	System	31 Mar 2021 13:17:47

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-03-31T09:17:44-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: 'db5d9885-ea27-4091-8ded-e3976deb3e46'	System	31 Mar 2021 13:17:47
User entered '31 Mar 2021 09:17:44'	System	31 Mar 2021 13:17:47

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-08T09:20:22-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '13112071-aef9-4946-9b1f-96a44841a5c3'	System	08 Apr 2021 13:20:34
User entered 'No (N)'	System	08 Apr 2021 13:20:34

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-08T09:20:24-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '13112071-aef9-4946-9b1f-96a44841a5c3'	System	08 Apr 2021 13:20:34
User entered 'No (N)'	System	08 Apr 2021 13:20:34

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-08T09:20:27-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '13112071-aef9-4946-9b1f-96a44841a5c3'	System	08 Apr 2021 13:20:34
User entered '08 Apr 2021 09:20:27'	System	08 Apr 2021 13:20:34

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-15T14:04:27-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4841962f-0a61-417b-ac2c-f7e8e2ac6b12'	System	15 Apr 2021 18:32:59
User entered 'No (N)'	System	15 Apr 2021 18:32:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-15T14:04:29-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4841962f-0a61-417b-ac2c-f7e8e2ac6b12'	System	15 Apr 2021 18:32:59
User entered 'No (N)'	System	15 Apr 2021 18:32:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-15T14:04:32-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '4841962f-0a61-417b-ac2c-f7e8e2ac6b12'	System	15 Apr 2021 18:32:59
User entered '15 Apr 2021 14:04:32'	System	15 Apr 2021 18:32:59

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-22T10:22:02-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '29c6c14b-90ce-4905-a600-14e31c9de1ff' User entered 'No (N)'	System	22 Apr 2021 14:22:11
	System	22 Apr 2021 14:22:11

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-22T10:22:04-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '29c6c14b-90ce-4905-a600-14e31c9de1ff'	System	22 Apr 2021 14:22:11
User entered 'No (N)'	System	22 Apr 2021 14:22:11

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-22T10:22:08-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '29c6c14b-90ce-4905-a600-14e31c9de1ff'	System	22 Apr 2021 14:22:11
User entered '22 Apr 2021 10:22:08'	System	22 Apr 2021 14:22:11

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-29T10:54:10-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '007b013b-df00-4b3c-a000-a2c3e2364eb5' User entered 'No (N)'	System	29 Apr 2021 15:15:18
	System	29 Apr 2021 15:15:18

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

Have you been exposed to someone with 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 (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-29T10:54:12-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '007b013b-df00-4b3c-a000-a2c3e2364eb5' User entered 'No (N)'	System	29 Apr 2021 15:15:18

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89832881-A6E2-4DFE-8AAA-3C231A5EE8E0)', Time: '2021-04-29T10:54:16-04:00', User OID: 'PatientReportedOutcome (US3742330)', ODM File OID: '007b013b-df00-4b3c-a000-a2c3e2364eb5'	System	29 Apr 2021 15:15:18
User entered '29 Apr 2021 10:54:16'	System	29 Apr 2021 15:15:18

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:31:55

US3742330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:32:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:31:55
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:31:55

US3742330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 17:23:10

US3742330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '04 Dec 2020'	Sherry McCammon (b) (4)	04 Dec 2020 17:23:10

US3742330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	04 Dec 2020 17:23:10

US3742330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	04 Dec 2020 17:23:10

US3742330

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 17:23:15

US3742330

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:40:22
User entered 'I'	System	04 Dec 2020 17:23:15

US3742330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:27:48

US3742330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '7 Jan 2021'	Sherry McCammon (b) (4)	12 Jan 2021 17:27:48

US3742330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:27:48

US3742330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	Sherry McCammon (b) (4)	12 Jan 2021 17:27:48

US3742330

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Jan 2021 17:28:03

US3742330

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User entered '1'	System	12 Jan 2021 17:28:03

US3742330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	08 Feb 2021 17:35:34

US3742330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '5 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	08 Feb 2021 17:35:34

US3742330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	08 Feb 2021 17:35:34

US3742330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	Sherry McCammon (b) (4)	08 Feb 2021 17:35:34

US3742330

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Feb 2021 17:35:41

US3742330

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:55:30
User entered 'I'	System	08 Feb 2021 17:35:41

US3742330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:32:14

US3742330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:32:14

US3742330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:32:14

US3742330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:32:14

US3742330

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:32:20

US3742330

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:09
User entered 'I'	System	12 Mar 2021 19:32:20

US3742330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:39:23

US3742330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 15:39:23

US3742330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 15:39:23

US3742330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered 'VISIT4'	System	24 Mar 2021 15:39:23

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered empty.	System	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered empty.	System	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered empty.	System	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered empty.	System	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered empty.	System	30 Mar 2021 19:12:48

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45

US3742330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45

US3742330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 15:40:09

US3742330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 15:40:09

US3742330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:39:50

US3742330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 15:39:50

US3742330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered '10:17'	(b) (4), (b) (6)	24 Mar 2021 15:39:50

US3742330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered '24 Mar 2021 10:17'	System	24 Mar 2021 15:39:50

US3742330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 15:39:58

US3742330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:45
User entered 'I'	System	24 Mar 2021 15:39:58

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per GCL Lab Recon: GCL has a swab sample with date of 28SEP2020 however Diagnostic Test form is not completed. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:08:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:27:52
Query 'Per GCL Lab Recon: GCL has a swab sample with date of 28SEP2020 however Diagnostic Test form is not completed. Please reconcile or clarify' answered with 'FORM COMPLETED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:22
User opened query 'Per GCL Lab Recon: GCL has a swab sample with date of 28SEP2020 however Diagnostic Test form is not completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:07:00
User entered '23 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:42:30

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:27:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 05:31:31
Query 'Data is required. Please complete.' answered with 'no time reported' (Site from System).	Sherry McCammon (b) (4)	02 Oct 2020 14:42:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Oct 2020 14:42:30
	Sherry McCammon (b) (4)	02 Oct 2020 14:42:30
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:22
User entered empty.	System	02 Oct 2020 14:42:30

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:27:52
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:42:30

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:32:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:27:52
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:42:30

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 1 (Day 1)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:29:48
User entered 'Day 13 (Day 13)'	(b) (4)	
	Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per CDM: It appears that Initial Start Date and Contact Date are the same 23SEP2020. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:15
Query 'Per CDM: It appears that Initial Start Date and Contact Date are the same 23SEP2020. Please review and reconcile.' answered with 'participant reported symptoms during contact call ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:27:15
User opened query 'Per CDM: It appears that Initial Start Date and Contact Date are the same 23SEP2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 13:44:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '23 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:29:48
User entered '1'	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:55:41
Query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' answered with 'ND-NOT DONE ENTERED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:23:24
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
User opened query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 13:48:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	25 Jan 2021 18:22:45
User entered empty.	System	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:44:35

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:44:35

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	02 Oct 2020 14:44:35
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 2 (Day 2)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '24 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:31:34
User entered '24 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:09

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:09

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	25 Jan 2021 18:22:45
User entered empty.	System	28 Oct 2020 13:31:09

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:09

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:09
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 3 (Day 3)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '25 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:24

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:24

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:24

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	25 Jan 2021 18:22:45
User entered empty.	System	28 Oct 2020 13:31:24

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:24

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 4 (Day 4)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '26 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	25 Jan 2021 18:22:45
User entered empty.	System	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:31:54

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:31:54
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 5 (Day 5)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '27 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	25 Jan 2021 18:22:45
User entered empty.	System	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:22:45
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 18:22:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:32:42

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:32:42
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 6 (Day 6)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:33:07

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:33:07

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '93' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	28 Oct 2020 13:34:28
User entered empty.	System	28 Oct 2020 13:33:07

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '098.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:33:07
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 7 (Day 7)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28

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Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '29 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:34:28

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:34:28

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '93' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:49:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	28 Oct 2020 13:49:06
User entered empty.	System	28 Oct 2020 13:34:28

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '097.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:49:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:35:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:36:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:38:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:39:32
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:40:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:41:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:42:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:43:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:44:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:45:15
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:34:28
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 8 (Day 8)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:48:20

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:48:20

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '91' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	28 Oct 2020 13:52:11
User entered empty.	System	28 Oct 2020 13:48:20

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '097.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:48:20

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:53:14
User entered 'Mild (Mild)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:48:20
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Day 9 (Day 9)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11

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Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '1 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '95'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User entered '%'	System	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered '096.4' F	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:55
User entered 'Mild (Mild)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:52:55
User entered 'Mild (Mild)'	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:32:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:02
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	28 Oct 2020 13:54:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	28 Oct 2020 13:52:11
	(b) (4)	

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered '28 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered '28 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:07
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:32:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:39
User entered '0'	System	28 Oct 2020 12:56:11

US3742330

Folder: Covid-19 Assessment 23 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:32:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:12:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:45:41

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	05 Nov 2020 18:16:04
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered '30 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:31

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:45:12

US3742330

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:32
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:32
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:32
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:58
User entered 'SICKD1'	System	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '10:00'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered '28 Sep 2020 10:00'	System	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '68.0' in	Sherry McCammon (b) (4)	29 Sep 2020 12:35:22
DataPoint set to visible.	(b) (4) System	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '307.6' lb	Sherry McCammon (b) (4)	29 Sep 2020 12:35:22
DataPoint set to visible.	(b) (4) System	29 Sep 2020 12:33:37

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '098.3' F	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '063'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered 'bpm'	System	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '20'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered 'breaths/min'	System	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '142'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered 'mmHg'	System	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:59
User entered '074'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11
User entered 'mmHg'	System	29 Sep 2020 12:35:22

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11

US3742330

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:11

US3742330

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:09
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:37:01

US3742330

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:09
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:37:01

US3742330

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:17
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 5 with date of 30SEP2020 however Saliva Log is not completed. Please reconcile and clarify ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:30:57
Query 'Per GCL Lab Recon: GCL has Saliva Day 5 with date of 30SEP2020 however Saliva Log is not completed. Please reconcile and clarify ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	05 Nov 2020 18:19:55
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 5 with date of 30SEP2020 however Saliva Log is not completed. Please reconcile and clarify ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:08:04
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:36:08

US3742330

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:32:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:38:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:30:17
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:36:08

US3742330

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

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:48:53

US3742330

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

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4)	15 Jan 2021 17:48:53
	(b) (4), (b) (6)	

US3742330

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

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:48:53

US3742330

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

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 17:48:53

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:15:39
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 15:15:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:52:36

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:15:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:10:52

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	15 Jan 2021 17:52:36
	(b) (4), (b) (6)	

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	12 Apr 2021 15:15:39
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	06 Mar 2021 19:10:52
	System	

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4)	15 Jan 2021 17:52:36
	(b) (4), (b) (6)	

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Placebo (Placebo)'	(b) (4)	15 Jan 2021 17:52:36
	(b) (4), (b) (6)	

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:45:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:52:36

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:45:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:52:36

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:52:36

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '1'	System	15 Jan 2021 17:52:36

US3742330

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

Form: Unblinding

Generated On: 10 Jun 2021 09:32:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'I'	System	15 Jan 2021 17:52:36

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered empty.	System	15 Jan 2021 17:56:20
DataPoint set to visible.	System	15 Jan 2021 17:52:36

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered empty.	System	15 Jan 2021 17:56:20
DataPoint set to visible.	System	15 Jan 2021 17:52:36

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '09:21'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '14 Jan 2021 09:21'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (Oral)'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '054'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'bpm'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'breaths/min'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '120'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '068'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:32:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered empty.	System	15 Jan 2021 17:56:20
DataPoint set to visible.	System	15 Jan 2021 17:52:36

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '10:08'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '14 Jan 2021 10:08'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (Other)'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '060'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'bpm'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '18'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'breaths/min'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '130'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '076'	(b) (4)	15 Jan 2021 17:56:20
	(b) (4), (b) (6)	

US3742330

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	15 Jan 2021 17:56:20

US3742330

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:53:22

US3742330

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4)	15 Jan 2021 17:53:22
	(b) (4), (b) (6)	

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	15 Jan 2021 17:53:43
	(b) (4), (b) (6)	

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	15 Jan 2021 17:53:43
	(b) (4), (b) (6)	

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

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 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:53:43

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mRNA-1273'	System	15 Jan 2021 17:53:43
DataPoint set to visible.	System	15 Jan 2021 17:52:36

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:53:43

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '09:38'	(b) (4)	15 Jan 2021 17:53:43
	(b) (4), (b) (6)	

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '14 Jan 2021 09:38'	System	15 Jan 2021 17:53:43

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:53:43

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'ONCE'	System	15 Jan 2021 17:53:43

US3742330

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

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 17:53:43

US3742330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:51:51

US3742330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4)	15 Jan 2021 17:51:51
	(b) (4), (b) (6)	

US3742330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '08:55'	(b) (4)	15 Jan 2021 17:51:51
	(b) (4), (b) (6)	

US3742330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '14 Jan 2021 08:55'	System	15 Jan 2021 17:51:51

US3742330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:52:10

US3742330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:52:10

US3742330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '08:59'	(b) (4)	15 Jan 2021 17:52:10
	(b) (4), (b) (6)	

US3742330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:32:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '14 Jan 2021 08:59'	System	15 Jan 2021 17:52:10

US3742330

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

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:53:13

US3742330

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

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '1'	System	15 Jan 2021 17:53:13

US3742330

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 19:03:09

US3742330

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '21 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	22 Jan 2021 19:03:09

US3742330

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Jan 2021 19:03:09

US3742330

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Jan 2021 19:03:09

US3742330

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 19:03:16

US3742330

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User entered 'I'	System	22 Jan 2021 19:03:16

US3742330

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:29
User entered 'I'	System	22 Jan 2021 19:03:16
DataPoint set to visible.	System	22 Jan 2021 19:03:16

US3742330

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:51:18

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '11 Feb 2021'	(b) (4)	11 Feb 2021 19:51:18
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:51:18

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'OLD29'	System	11 Feb 2021 19:51:18

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '09:11'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '11 Feb 2021 09:11'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (Oral)'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '060'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'bpm'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'breaths/min'	System	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '107'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '073'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:32:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '09:55'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '11 Feb 2021 09:55'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4)	11 Feb 2021 20:00:33
User entered 'Other (Other)' reason for change: Data Entry Error	System	11 Feb 2021 20:00:33
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 19:59:12
User entered 'Oral (Oral)'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '060'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'bpm'	System	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'breaths/min'	System	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '118'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	11 Feb 2021 19:59:12

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '068'	(b) (4)	11 Feb 2021 19:59:12
	(b) (4), (b) (6)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:32:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mmHg'	System	11 Feb 2021 19:59:12

US3742330

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	11 Feb 2021 19:52:11
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '11 Feb 2021'	(b) (4)	11 Feb 2021 19:52:11
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	11 Feb 2021 19:52:33
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	11 Feb 2021 19:52:33
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

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 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'mRNA-1273'	System	11 Feb 2021 19:52:33
DataPoint set to visible.	System	22 Jan 2021 19:03:16

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '09:24'	(b) (4)	11 Feb 2021 19:52:33
	(b) (4), (b) (6)	

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered '11 Feb 2021 09:24'	System	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'ONCE'	System	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:32:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 19:52:33

US3742330

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:51:33

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:20:54
User entered 'I'	System	11 Feb 2021 19:51:33

US3742330

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 20:49:27
	(b) (4), (b) (6)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:49:27

US3742330

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:49:27

US3742330

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:32:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	19 Feb 2021 20:49:27
	(b) (4), (b) (6)	

US3742330

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:49:32

US3742330

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:32:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:01:52
User entered 'I'	System	19 Feb 2021 20:49:32

US3742330

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:10:59

US3742330

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:10:59

US3742330

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[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 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:10:59

US3742330

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:32:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered 'OLD57'	System	26 Mar 2021 19:10:59

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered empty.	System	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered empty.	System	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered empty.	System	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered empty.	System	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered empty.	System	26 Mar 2021 19:11:16

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57

US3742330

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:32:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57

US3742330

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:24

US3742330

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:32:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:24

US3742330

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:39

US3742330

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:39

US3742330

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered '10:17'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:11:39

US3742330

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:57
User entered '24 Mar 2021 10:17'	System	26 Mar 2021 19:11:39

US3742330

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:32:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	29 Sep 2020 12:42:31

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:53:29
Query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'YES ASSESSED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:30:20
User opened query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:14:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:04:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:04:47
Data point term sent to Coder	System	02 Oct 2020 19:03:34
User closed query 'For coding purposes, please specify type of CONGESTION, (e.g. Nasal, lung, respiratory tract, etc) and update the term with your response.' (Site from System).	System	02 Oct 2020 19:03:11
Query 'For coding purposes, please specify type of CONGESTION, (e.g. Nasal, lung, respiratory tract, etc) and update the term with your response.' answered with 'UPDATED' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 19:03:11
User entered 'NASAL CONGESTION' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 19:03:03
User opened query 'For coding purposes, please specify type of CONGESTION, (e.g. Nasal, lung, respiratory tract, etc) and update the term with your response.' (Site from System).	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:56:32
Data point term sent to Coder	System	29 Sep 2020 12:46:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'congestion'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:55:24
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Updated to reflect unsolicited event ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:12:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:12:08
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:27:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	02 Oct 2020 14:38:44
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:38:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:38:44
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	02 Oct 2020 14:38:44
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 12:45:51
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '23 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User entered empty.	System	29 Sep 2020 12:45:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '28 Sep 2020'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User entered empty.	System	29 Sep 2020 12:45:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:38:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:38:44
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:38:44
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 12:45:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:38:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:38:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:38:44
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 12:45:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:38:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:38:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	02 Oct 2020 14:38:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 12:45:51
	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:38:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:38:44
User entered 'None (NONE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	02 Oct 2020 14:38:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 12:45:51
	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'l'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:03:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 19:03:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 19:03:03
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 12:45:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[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 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User entered '0'	System	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04
User entered '0'	System	29 Sep 2020 12:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:53:51
Query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'YES ASSESSED - COVID 19 NEGATIVE' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:31:07
User opened query 'Per MM, this subject presented nasal congestion, cough - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:14:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:40:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:40:46
Data point term sent to Coder	System	02 Oct 2020 14:40:14
User entered 'cough'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:55:29
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Updated to reflect unsolicited event' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:13:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:13:42
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:27:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '23 Sep 2020'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User entered empty.	System	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '28 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User entered empty.	System	02 Oct 2020 14:40:03

US3742330

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:40:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:40:35
User entered 'None (NONE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	02 Oct 2020 14:40:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Oct 2020 14:40:03
	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'l'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:03:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 19:03:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 19:03:51
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:40:03
User entered empty.	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[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 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		11 Dec 2020 22:08:21
User entered empty.	Sherry McCammon (b) (4)	02 Oct 2020 14:40:03
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User entered '0'	System	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53
User entered '0'	System	02 Oct 2020 14:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Sinus headache, LLT: Sinus headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:52:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:52:28
Data point term sent to Coder	System	09 Oct 2020 18:51:46
User entered 'SINUS HEADACHE'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '22 Sep 2020'	(b) (4), (b) (6)	11 Dec 2020 22:08:21
	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User entered empty.	System	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered '29 Sep 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Oct 2020 20:32:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User entered empty.	System	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 20:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 20:32:45
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	20 Oct 2020 20:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
		09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:50:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 15:50:14
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 15:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:50:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	21 Oct 2020 15:50:14
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	09 Oct 2020 18:51:30
User entered empty.	(b) (4)	09 Oct 2020 18:51:30
	(b) (4), (b) (6)	

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:50:14
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 15:50:14
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Oct 2020 15:50:14
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Oct 2020 18:51:30
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	
	Kaitlin Mason (b) (4)	21 Oct 2020 15:50:14
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:50:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 15:50:14
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 18:51:30
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[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 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:51:30

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User entered '0'	System	20 Oct 2020 20:32:45

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39
User entered '0'	System	20 Oct 2020 20:32:45

US3742330

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:59:39

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:19:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:19:56
Data point term sent to Coder	System	30 Oct 2020 15:46:07
User entered 'left arm pain from seasonal flu injection'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered '27 Oct 2020'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User entered empty.	System	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '27 Oct 2020'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User entered empty.	System	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:07:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:07:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:07:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:45:43
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:44:52
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'changed' (Site from DM).	Sherry McCammon (b) (4)	12 Jan 2021 17:36:23
DataPoint Un-verified.	(b) (4)	
User entered '0' reason for change: New Information	Sherry McCammon (b) (4)	12 Jan 2021 17:36:04
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Dec 2020 13:38:05
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 14:07:19
User entered '1' reason for change: New Information	Hassan Haji (b) (4)	02 Nov 2020 14:07:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	30 Oct 2020 15:45:43
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	12 Jan 2021 17:36:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 17:36:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4)	30 Oct 2020 15:45:43
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[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 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4)	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User entered '0'	System	30 Oct 2020 15:45:43

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51
User entered '0'	System	02 Nov 2020 14:07:19

US3742330

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:15:56
User entered	System	02 Dec 2020 16:15:47
'USA-US127-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 16:15:47

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:19:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:19:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:57
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'PV Query: Please clarify whether the event occurred from congestive heart failure? If so, please reconsider the event term.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:39:31
Query 'PV Query: Please clarify whether the event occurred from congestive heart failure? If so, please reconsider the event term.' answered with 'The event began prior the the clinical diagnosis of CHF' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 20:47:15
User opened query 'PV Query: Please clarify whether the event occurred from congestive heart failure? If so, please reconsider the event term.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:41:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:33:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:33:03
Data point term sent to Coder	System	04 Dec 2020 19:46:38
User entered 'ACUTE HYPOXEMIC RESPIRATORY FAILURE' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	04 Dec 2020 19:46:28

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Dec 2020 19:46:57
Coding entries removed.	Kaitlin Mason (b) (4)	01 Dec 2020 19:46:09
	(b) (4)	
User entered 'SHORTNESS OF BREATH with Hypoxemia' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 19:46:09
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4)	30 Nov 2020 20:53:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Nov 2020 20:53:01
	(b) (4)	
Data point term sent to Coder	System	30 Nov 2020 20:51:57
User entered 'shortness of breath'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 18:13:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 18:13:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 18:13:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:51:37
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (28-Nov-2020).' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:40:29
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (28-Nov-2020).' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	09 Dec 2020 20:49:47
	(b) (4)	
User entered '28 Nov 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 20:49:36
	(b) (4)	
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (28-Nov-2020).' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:37:57
User entered '29 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Dec 2020 17:26:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	23 Dec 2020 18:46:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Dec 2020 18:46:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Dec 2020 21:16:10
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Dec 2020 17:27:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Dec 2020 17:27:13
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Dec 2020 17:26:08
User entered '03 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Dec 2020 17:26:08
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	01 Dec 2020 18:16:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 17:55:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 17:55:45
User entered 'Yes (Y)' reason for change: New Information	Kaitlin Mason (b) (4)	01 Dec 2020 17:55:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:51:37
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
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)	07 Dec 2020 23:34:03
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 'participant has not been discharged' (Site from System).	Kaitlin Mason (b) (4)	01 Dec 2020 17:58:31
	(b) (4)	
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	01 Dec 2020 17:55:45
User entered '1' reason for change: New Information	Kaitlin Mason (b) (4)	01 Dec 2020 17:55:45
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'PV Query: Please confirm hospital admission date. The narrative reports "transferred to inpatient on 30 Nov 2020".' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:40:36
Query 'PV Query: Please confirm hospital admission date. The narrative reports "transferred to inpatient on 30 Nov 2020".' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4)	09 Dec 2020 20:50:46
	(b) (4)	
User opened query 'PV Query: Please confirm hospital admission date. The narrative reports "transferred to inpatient on 30 Nov 2020".' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:38:23
User entered '29 Nov 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 17:55:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

US3742330

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'PATIENT WAS DISCHARGED WITH O2. PATIENT ALSO RECIEVED NEG COVID TEST' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:15:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:58:41
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:40:54
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 20:51:37
User entered '03 Dec 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 20:51:04
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:37:26
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 17:55:45
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Not Related (NOT RELATED)'	Kaitlin Mason (b) (4)	01 Dec 2020 18:16:04
reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please	System	01 Dec 2020 18:13:35
complete.' (Site from System).		
Query 'Data is required. Please complete.' answered	System	01 Dec 2020 18:13:35
by data change (Site from System).		
User entered 'Not Applicable (NOT APPLICABLE)'	Kaitlin Mason (b) (4)	01 Dec 2020 18:13:35
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please	System	30 Nov 2020 20:51:37
complete.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Not Related (NOT RELATED)'	Kaitlin Mason (b) (4)	01 Dec 2020 18:16:04
reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please	System	01 Dec 2020 18:13:35
complete.' (Site from System).		
Query 'Data is required. Please complete.' answered	System	01 Dec 2020 18:13:35
by data change (Site from System).		
User entered 'Not Applicable (NOT APPLICABLE)'	Kaitlin Mason (b) (4)	01 Dec 2020 18:13:35
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please	System	30 Nov 2020 20:51:37
complete.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Form: Adverse Events (5)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 18:13:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 18:13:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 18:13:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:51:37
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Dec 2020 18:13:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Nov 2020 20:51:37
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	01 Dec 2020 18:13:35
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 21:33:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kaitlin Mason (b) (4)	23 Dec 2020 18:46:17
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 21:16:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 21:16:10
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Dec 2020 17:27:13
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Per DM CLR: SAE Narrative = BILATERAL PLEURAL EFFUSIONS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 08:42:08
User closed query 'Per DM CLR: SAE Narrative = PARTICIPANT HAD CHEST CT 29 NOV. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 08:42:03
Query 'Per DM CLR: SAE Narrative = BILATERAL PLEURAL EFFUSIONS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'PLEURAL EFFUSIONS PART OF CHF DIAGNOSIS AND NOT A SEPARATE AE' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:55:07
Query 'Per DM CLR: SAE Narrative = PARTICIPANT HAD CHEST CT 29 NOV. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'RECORDED ON THE CONPROC ECRF' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:54:09
User opened query 'Per DM CLR: SAE Narrative = BILATERAL PLEURAL EFFUSIONS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:42:14
User opened query 'Per DM CLR: SAE Narrative = PARTICIPANT HAD CHEST CT 29 NOV. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:41:48

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:55:16
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'redacted copy sent' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:12:47
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 14:51:24
User closed query 'PV Query: Please confirm if the subject was discharged on home oxygen.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:12:20
User closed query 'PV Query: Please provide the results of any COVID 19 testing done while inpatient. If no tests were performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:12:16
Query 'PV Query: Please provide the results of any COVID 19 testing done while inpatient. If no tests were performed, please state so.' answered with 'per participant - tested negative for SARS-Cov-2 at Kaiser Permanente ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	16 Dec 2020 17:09:05
Query 'PV Query: Please confirm if the subject was discharged on home oxygen.' answered with 'per discharge medication list, participant was not discharged on home oxygen ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	16 Dec 2020 17:07:22
User closed query 'PV Query: As the discharge diagnosis was also include acute exacerbation of diastolic CHF (reported as a new finding), please consider adding this as separate event.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 02:33:30

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As the discharge diagnosis was also include acute exacerbation of diastolic CHF (reported as a new finding), please consider adding this as separate event.' answered with 'Added to AE' (Site from Safety).	Sherry McCammon (b) (4)	15 Dec 2020 18:20:21
User opened query 'PV Query: As the discharge diagnosis was also include acute exacerbation of diastolic CHF (reported as a new finding), please consider adding this as separate event.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:48:28
User opened query 'PV Query: Please confirm if the subject was discharged on home oxygen.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:48:17
User opened query 'PV Query: Please provide the results of any COVID 19 testing done while inpatient. If no tests were performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:48:02
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'PV Query: Please kindly provide information on investigations (vitals, imaging diagnosis other than CT, ECG, UCG, blood analysis of troponin, and cultures), treatments, and final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 03:02:44
Query 'PV Query: Please kindly provide information on investigations (vitals, imaging diagnosis other than CT, ECG, UCG, blood analysis of troponin, and cultures), treatments, and final diagnosis.' answered with 'discharge diagnosis was "acute hypoxemix respiratory failure likely due to acute exacerbation of diastolic CHF (new diagnosis)"	Kaitlin Mason (b) (4)	09 Dec 2020 21:09:08
Prior to seeing per PCP, participant checked her pulse ox at home and noted 78% on room air.	(b) (4)	
As of 03 DEC2020 Resting O2 = 92% on room air, 87% while ambulating, and back up to 94% at rest with 2L oxygen.		
30 NOV 2020 BNP was 318 (ref: <=100pg/mL) ' (Site from Safety).		

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT REPORTS SHORTNESS OF BREATH WITH SELF REPORTED HYPOXEMIA BEGINNING NOVEMBER 28 2020. PARTICIPANT WENT TO PRIMARY DOCTOR AT KAISER PERMANENTE NOVEMBER 29TH WHERE SHE TESTED NEGATIVE FOR SARS-COV-2. WAS TRANSFERRED TO INPATIENT CARE late NOVEMBER 29TH WHERE SHE IS UNDERGOING EVALUATION FOR PROBABLE CONGESTIVE HEART FAILURE. PARTICIPANT HAD CHEST CT 29 NOV THAT SHOWED BILATERAL PLEURAL EFFUSIONS BUT NO SIGNS OF COVID INFECTION. LAB VALUES REPORTED ARE WITHIN NORMAL LIMITS AND PARTICIPANT STARTED COURSE OF IV LASIX AND HOSPITAL ANTICOAGULATION.'	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 20:51:04
reason for change: Data Entry Error User opened query 'PV Query: Please kindly provide information on investigations (vitals, imaging diagnosis other than CT, ECG, UCG, blood analysis of troponin, and cultures), treatments, and final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:41:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Dec 2020 18:50:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Dec 2020 18:50:08
User entered 'Participant reports shortness of breath with self reported hypoxemia beginning November 28 2020. Participant went to primary doctor at Kaiser Permanente November 29th where she tested negative for SARS-CoV-2. Was transferred to inpatient care November 30th where she is undergoing evaluation for probable congestive heart failure. Participant had chest CT 29 NOV that showed bilateral pleural effusions but no signs of covid infection. Lab values reported are within normal limits and participant started course of IV lasix and hospital anticoagulation.' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	01 Dec 2020 18:50:08

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Dec 2020 17:55:45
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:51:37

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 17:55:45

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 18:13:35

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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)
User entered '0'	System	01 Dec 2020 17:55:45

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 13:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 13:57:43
Data point term sent to Coder	System	07 Dec 2020 13:56:19
User entered 'diastolic congestive heart failure'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 16:29:53
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 16:29:53
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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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)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	08 Dec 2020 16:29:53
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '26 Nov 2020'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 13:55:33

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Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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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)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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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	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

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Generated On: 10 Jun 2021 09:32:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 16:29:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 16:29:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 13:55:33
User entered empty.	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Dec 2020 16:29:53
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Dec 2020 16:29:53
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Dec 2020 13:55:33
User entered '0'	Hassan Haji (b) (4)	07 Dec 2020 13:55:33
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Dec 2020 13:55:33

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 16:29:53

US3742330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 16:29:53

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:19:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:19:52
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 21:18:17
User entered 'ATRIAL FIBRILATION'	(b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Dec 2020 21:17:58

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Arteriosclerosis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:38:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:38:09
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 21:14:48
User entered 'Arteriosklerosis'	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '29 Nov 2020'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Jan 2021 21:15:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 21:15:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Jan 2021 21:14:40
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 21:14:40

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 16:09:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 16:09:07
Data point term sent to Coder	System	26 Jan 2021 13:05:14
User entered 'chronic kidney disease state 3'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
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	02 Feb 2021 17:15:23
User entered 'Yes (Y)' reason for change: Data Entry Error	System	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
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	02 Feb 2021 17:15:23
User entered 'No (N)' reason for change: Data Entry Error	System	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '3 Dec 2020'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User entered empty.	System	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User entered empty.	System	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	02 Feb 2021 17:16:26
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 17:15:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 17:15:23
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	02 Feb 2021 17:15:23
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:16:26
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:16:26
	(b) (4)	
User entered '29 Nov 2020'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:16:26
	(b) (4)	
User entered '3 Dec 2020'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	02 Feb 2021 17:16:26
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
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	02 Feb 2021 17:15:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
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	02 Feb 2021 17:15:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
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	02 Feb 2021 17:15:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	02 Feb 2021 17:15:23
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
User entered empty.	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	23 Feb 2021 18:59:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 18:59:36
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Feb 2021 18:59:21
User entered '0' reason for change: Data Entry Error		28 Jan 2021 20:41:35
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	Kaitlin Mason (b) (4)	28 Jan 2021 20:41:35
User entered '1'	(b) (4)	
	System	26 Jan 2021 13:04:52
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:09:33
' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	23 Feb 2021 18:59:46
' answered with 'updated' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:59:21
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	08 Feb 2021 13:46:38
' (Site from DM). User entered '1'	Sherry McCammon (b) (4) (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered '0'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Kaitlin Mason (b) (4)	02 Feb 2021 17:15:23
reason for change: Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

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 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'Participant has reached new baseline - CKD continues but is stable' reason for change: Data Entry Error	System	02 Feb 2021 17:16:26
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	Kaitlin Mason (b) (4)	02 Feb 2021 17:16:26
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:35:21
User entered empty.	Sherry McCammon (b) (4)	26 Jan 2021 13:04:52

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User entered '0'	System	02 Feb 2021 17:15:23

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User entered 'I'	System	02 Feb 2021 17:15:23

US3742330

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:43
User entered '0'	System	26 Jan 2021 13:04:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:32:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:54:53

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 19:56:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:56:50
Data point term sent to Coder	System	11 Sep 2020 19:56:31
User entered 'amlopdipine'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'hypertension'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:07:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '10'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'UN UNK 2005'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 19:56:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:56:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:56:25

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:00:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:00:41
Data point term sent to Coder	System	11 Sep 2020 19:59:37
User entered 'metoprolol'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:58:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'hypertension'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 19:58:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '100qAM, 50qPM'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'twice daily (BID)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'UN UNK 2005'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 19:58:49
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Sep 2020 19:58:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:58:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:58:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:03:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:03:52
Data point term sent to Coder	System	11 Sep 2020 20:02:41
User entered 'atorvastatin'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:02:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'hypercholesterolemia'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '10'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'UN UNK 2010'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	11 Sep 2020 20:02:20
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:02:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 20:02:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 20:02:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:05:45
Data point term sent to Coder	System	11 Sep 2020 20:04:43
User entered 'furosemide'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'fluid retention'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '20'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '5 Aug 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:00:34
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:00:34
User entered empty.	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User entered '1'	System	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User entered '1'	System	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:07
User entered '804 (804)'	System	11 Sep 2020 20:03:49

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 20:06:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:06:48
Data point term sent to Coder	System	11 Sep 2020 20:05:44
User entered 'aspirin'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'cardiac'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '81'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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	11 Sep 2020 20:06:44
User entered 'mg (mg)' reason for change: Data Entry Error	System	11 Sep 2020 20:06:44
User opened query 'Data is required. Please complete.' (Site from System).	Hassan Haji (b) (4)	11 Sep 2020 20:06:44
User entered empty.	(b) (4)	
	System	11 Sep 2020 20:05:21
	Hassan Haji (b) (4)	11 Sep 2020 20:05:21
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'UN UNK 1985'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	12 Jan 2021 17:37:18
User entered 'Yes (Y)'	(b) (4)	
	Hassan Haji (b) (4)	11 Sep 2020 20:05:21
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	12 Jan 2021 17:37:18
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	11 Sep 2020 20:05:21
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User entered '1'	System	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User entered '1'	System	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:11
User entered '804 (804)'	System	11 Sep 2020 20:05:21

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:07:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:07:38
Data point term sent to Coder	System	11 Sep 2020 20:06:47
User entered 'allegra'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'sinus congestion'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:07:27
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 19:23:18
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:57:39
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 18:57:29
User entered '180' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 18:57:29
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:43:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '10'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'mg (mg)'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:04:17
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'The con med started the same year as the MH 2010' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:31:56
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:43:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'UN UNK 2010'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:05:52
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'UN Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:05:52
User entered empty.	Hassan Haji (b) (4) (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User entered '1'	System	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User entered '1'	System	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:09:53
User entered '804 (804)'	System	11 Sep 2020 20:06:28

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 13:58:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 13:58:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
Data point term sent to Coder	System	02 Feb 2021 17:22:14
Coding entries removed.	Kaitlin Mason (b) (4)	02 Feb 2021 17:22:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN;DOXYLAMINE;PARA CETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:51:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:51:17
Data point term sent to Coder	System	09 Nov 2020 21:12:37
User closed query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	09 Nov 2020 21:12:32
Query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:12:32
Coding entries removed.	(b) (4), (b) (6)	09 Nov 2020 21:12:22
User entered 'NYQUIL (650 mg. Acetaminophen, 30 mg. Dextromethorphan, 12.5 mg. Doxylamine)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:12:22

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
User opened query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:55:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:12:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:12:39
Data point term sent to Coder	System	28 Sep 2020 14:11:58
User entered 'NYQUIL'	(b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR: Please note that EXACERBATION OF SEASON ALLERGIES is not recorded as an AE. However, NASAL CONGESTION, COUGH, & SINUS HEADACHE are recorded as AEs. Please review if this medication was used for those. If Yes, please update the indication and the AE's Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please note that EXACERBATION OF SEASON ALLERGIES is not recorded as an AE. However, NASAL CONGESTION, COUGH, & SINUS HEADACHE are recorded as AEs. Please review if this medication was used for those. If Yes, please update the indication and the AE's Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:04:21
User entered 'Nasal congestion' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:22:14 02 Feb 2021 17:22:07
User opened query 'Per DM CLR: Please note that EXACERBATION OF SEASON ALLERGIES is not recorded as an AE. However, NASAL CONGESTION, COUGH, & SINUS HEADACHE are recorded as AEs. Please review if this medication was used for those. If Yes, please update the indication and the AE's Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 07:20:25
User entered 'EXACERBATION OF SEASON ALLERGIES'	(b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '2'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Hassan Haji (b) (4)	30 Oct 2020 15:37:49
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:05:29
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'as per participant verbal report. medication still ongoing' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:45:40
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:56:04
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty; reason for change New Information	(b) (4) Hassan Haji (b) (4)	30 Oct 2020 15:37:49
User entered '22 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:05:22
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:44:20
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:44:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 17:44:07
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:56:37
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:02:11

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:11:08

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 14:12:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:12:39
Data point term sent to Coder	System	28 Sep 2020 14:11:59
User entered 'MOTRIN'	(b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'SINUS HEADACHE'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '800'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 14:48:33
User entered '7 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Oct 2020 18:42:50
User entered '22 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:35:55
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'Corrected' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	07 Dec 2020 14:48:26
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	07 Dec 2020 14:48:17
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 13:56:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:11:50

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User entered empty.	System	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User entered empty.	System	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:15
User entered empty.	System	28 Sep 2020 14:11:50

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 18:45:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:45:31
Data point term sent to Coder	System	09 Oct 2020 18:44:32
User entered 'TYLENOL'	(b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'SINUS HEADACHE'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User entered empty.	System	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User entered empty.	System	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:20
User entered empty.	System	09 Oct 2020 18:44:24

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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 of STAGE 2 RENAL INSUFFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:03:49
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 of STAGE 2 RENAL INSUFFICIENCY should be recorded, and update con med indication or provide clarification. ' answered with 'not related to this time frame' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:22:57
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 of STAGE 2 RENAL INSUFFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 06:04:15
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.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:52:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:52:30
Data point term sent to Coder	System	23 Oct 2020 19:30:13
User entered 'losartan'	Hassan Haji (b) (4) (b) (4)	23 Oct 2020 19:29:44

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'renal insufficiency'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '100'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '19 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	23 Oct 2020 19:29:44
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:29:44

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:29:44

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 19:29:44

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:42:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:42:00
Data point term sent to Coder	System	30 Oct 2020 15:41:04
User entered 'Tylenol'	Hassan Haji (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'left arm pain from seasonal influenza vaccine'	(b) (4) Hassan Haji (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:04:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'As per verbal report from participant dose is 800mg ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:36:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:57:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '800'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '27 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '27 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 08:18:20
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'it is marked as no' (Site from DM).	Sherry McCammon (b) (4)	22 Jan 2021 19:09:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 17:51:56
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 07:20:59
User entered 'Yes (Y)'	Hassan Haji (b) (4)	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User entered empty.	System	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User entered empty.	System	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:29
User entered empty.	System	30 Oct 2020 15:40:20

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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)	30 Oct 2020 15:42:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 15:42:53
Data point term sent to Coder	System	30 Oct 2020 15:42:04
User entered 'high dose influenza vaccine'	Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'influenza prophylaxis'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0.7'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 08:10:44
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Sherry McCammon (b) (4)	22 Jan 2021 19:09:47
User entered 'mL (mL)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	22 Jan 2021 19:09:39
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 05:57:41
User entered 'mg (mg)'	Hassan Haji (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '27 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '27 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User entered empty.	System	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User entered empty.	System	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:30
User entered empty.	System	30 Oct 2020 15:41:55

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	03 Feb 2021 00:43:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	03 Feb 2021 00:43:34
Data point term sent to Coders	System	02 Feb 2021 17:25:16
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:24:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	30 Nov 2020 23:38:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	30 Nov 2020 23:38:08
Data point term sent to Coders	System	30 Nov 2020 20:49:55
User entered 'Furosemide'	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR: Please note there is a medical condition if ACUTE HYPOXEMIC RESPIRATORY FAILURE recorded in AE eCRF during this timeframe. Please confirm if this Con Med is given for this medication condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:23:30
Query 'Per DM CLR: Please note there is a medical condition if ACUTE HYPOXEMIC RESPIRATORY FAILURE recorded in AE eCRF during this timeframe. Please confirm if this Con Med is given for this medication condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:24:38
User entered 'acute hypoxemic respiratory failure' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:24:17
User opened query 'Per DM CLR: Please note there is a medical condition if ACUTE HYPOXEMIC RESPIRATORY FAILURE recorded in AE eCRF during this timeframe. Please confirm if this Con Med is given for this medication condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:27:55
User entered 'shortness of breath'	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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	01 Dec 2020 19:05:56
User entered '80' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:05:56
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:49:14
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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	01 Dec 2020 19:05:56
User entered 'mg (mg)' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:05:56
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:49:14
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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	01 Dec 2020 19:05:56
User entered 'twice daily (BID)' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:05:56
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:49:14
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	04 Dec 2020 17:24:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:24:34
	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
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	01 Dec 2020 19:05:56
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 19:05:56
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 20:49:14
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User entered '2'	System	01 Dec 2020 19:05:56
User entered empty.	System	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User entered '1'	System	01 Dec 2020 19:05:56
User entered empty.	System	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:33
User entered '804 (804)'	System	01 Dec 2020 19:05:56
User entered empty.	System	30 Nov 2020 20:49:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT THROMBIN INHIBITORS, PRODUCT: DABIGATRAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Feb 2021 17:27:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 17:27:30
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4)	02 Feb 2021 17:26:19 02 Feb 2021 17:25:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT THROMBIN INHIBITORS, PRODUCT: DABIGATRAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 06:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:54:44
Data point term sent to Coder User entered 'Dabigatran'	System (b) (4), (b) (6)	01 Dec 2020 19:11:46 01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of its drug classification. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:23:51
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of its drug classification. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:26:34
User entered 'atrial fibrillation' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 17:25:48
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of its drug classification. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:07:09
User entered 'Hospital Anticoagulation'	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '150'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 19:11:07

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Jan 2021 22:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 22:19:42
Data point term sent to Coder	System	12 Jan 2021 17:43:20
User entered 'Oxygen'	Sherry McCammon (b) (4) (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'acute hypoxemic respiratory failure'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'liter'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'as needed (PRN)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Nasal (NASAL)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '3 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
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)	16 Apr 2021 09:04:51
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
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) (4), (b) (6)	12 Apr 2021 15:20:01
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 15:19:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 15:19:41
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)	11 Mar 2021 08:55:52
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:47:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:19:41
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 15:19:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User entered empty.	System	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User entered empty.	System	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:44
User entered empty.	System	12 Jan 2021 17:43:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User closed query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION RIGHT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:05:28
Query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION RIGHT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening. ' (Site from DM).	Sherry McCammon (b) (4)	07 Apr 2021 17:48:41
User opened query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION RIGHT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:46:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 21:43:59
Data point term sent to Coder	System	12 Jan 2021 17:49:23
Data point term sent to Coder	System	12 Jan 2021 17:47:22
User entered 'corticosteroid injection right knee'	Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'ostearthritis'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'unknown'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4)	12 Jan 2021 17:49:04
User entered 'unknown' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 17:49:04
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Jan 2021 17:46:30
User entered empty.	Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once (ONCE)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'intraarticular' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	12 Jan 2021 17:49:04
User entered 'injection'	(b) (4)	
	Sherry McCammon (b) (4)	12 Jan 2021 17:46:30
	(b) (4)	

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '6 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '6 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User entered empty.	System	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User entered empty.	System	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:46
User entered empty.	System	12 Jan 2021 17:46:30

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User closed query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION LEFT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:07:26
Query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION LEFT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening' (Site from DM).	Sherry McCammon (b) (4)	07 Apr 2021 17:48:50
User opened query 'Per DM CLR: Con Med CORTICOSTEROID INJECTION LEFT KNEE was added/changed on 6 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:45:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Jan 2021 21:43:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:43:59
Data point term sent to Coder	System	12 Jan 2021 17:49:23
User entered 'corticosteroid injection left knee'	Sherry McCammon (b) (4) (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'osteoarthritis'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'unknown'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'unknown'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once (ONCE)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'interarticular'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '6 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '6 Jan 2021'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User entered empty.	System	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User entered empty.	System	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:29:47
User entered empty.	System	12 Jan 2021 17:48:29

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med FLONASE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:07:37
Query 'Per DM CLR: Con Med FLONASE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with ' con med added as participant's healthcare provider's judgement. no worsening . no AE needed' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 18:05:54
User opened query 'Per DM CLR: Con Med FLONASE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:46:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 18:25:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:25:57
Data point term sent to Coder	System	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Flonase'	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Sinus congestion'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '200'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Other (OTHER)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mcg'	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Nasal (NASAL)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '30 Dec 2020'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 18:25:14

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:28:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:28:56
Data point term sent to Coder	System	15 Jan 2021 18:28:18
User entered 'Furosemide'	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Fluid retention'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '20'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'every other day (QOD)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '30 Nov 2020'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 18:27:58

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User closed query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:07:49
Query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'con med add per participant's healthcare provider's decision. no worsening of medical history' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:47:37
User opened query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:19:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE, PRODUCTSYNONYM: ALDACTONE [SPIRONOLACTONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:49:45
Data point term sent to Coder	System	19 Feb 2021 20:53:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Aldactone'	(b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Fluid retention'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '25'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User entered '1'	System	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User entered '1'	System	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:30:05
User entered '804 (804)'	System	19 Feb 2021 20:52:10

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:07:57
Query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'dose of con med decreased from 25 mg down to 12.5mg. no AE needed. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 18:10:40
User opened query 'Per DM CLR: Con Med ALDACTONE was added/changed on 30 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:18:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE, PRODUCTSYNONYM: ALDACTONE [SPIRONOLACTONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Feb 2021 13:49:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 13:49:46
Data point term sent to Coder	System	19 Feb 2021 20:55:16

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Aldactone'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Fluid retention'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '12.5'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:32:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 20:54:41

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:32:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Feb 2021 17:36:56

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:32:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '29 Dec 2020'	Sherry McCammon (b) (4)	08 Feb 2021 17:39:07
	(b) (4)	

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:32:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'CHEST CT FOR EVAULATION OF CHF'	Sherry McCammon (b) (4)	08 Feb 2021 17:39:07
	(b) (4)	

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered 'Adverse Event (AE)'	Sherry McCammon (b) (4)	08 Feb 2021 17:39:07
	(b) (4)	

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:32:31

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Feb 2021 17:39:07
	(b) (4)	

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:35:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:31:35

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:35:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Sleep Study'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:31:35

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:35:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:31:35

US3742330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:32:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:35:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:37:51
User entered 'Rule out sleep apnea'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:31:35

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'USA-US127-2020-MRNA-1273-P301000012'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered	System	02 Dec 2020 16:15:47
'USA-US127-2020-MRNA-1273-P301000012'		

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
User entered '02/Dec/2020 16:17'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:32:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'USA-US127-2020-MRNA-1273-P301000012'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
User entered '05/Dec/2020 16:49'	System	05 Dec 2020 16:49:03

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:32:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
User entered 'I'	(b) (4), (b) (6)	05 Dec 2020 16:49:03

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'USA-US127-2020-MRNA-1273-P301000012'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
User entered '10/Dec/2020 15:42'	System	10 Dec 2020 20:42:35

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:32:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:46
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 20:42:35

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered	System	02 Dec 2020 16:15:47
'USA-US127-2020-MRNA-1273-P301000012'		

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:37
User entered '22/Dec/2020 10:10'	System	22 Dec 2020 18:10:06

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:32:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 21:32:37
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:34:06
User entered '1'	(b) (4), (b) (6)	22 Dec 2020 18:10:06

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'USA-US127-2020-MRNA-1273-P301000012'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Yes (Y)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'No (N)'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Karen'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Kotloff'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '685 W. Baltimore Street, HSF 480'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered 'Baltimore'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:41:34
Un-reviewed for Safety.	System	05 Dec 2020 16:49:03
User entered empty.	System	05 Dec 2020 16:49:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'MD'	Sherry McCammon (b) (4)	04 Dec 2020 17:28:40
	(b) (4)	

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 16:17:20
User entered '21201'	System	02 Dec 2020 16:15:47

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 22:08:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:48:53
User entered 'US'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:32:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
	(b) (4)	
User entered '5'	System	28 Dec 2020 15:34:30
User entered '4'	System	22 Dec 2020 18:10:06
User entered '3'	System	10 Dec 2020 20:42:35
User entered '2'	System	05 Dec 2020 16:49:03
User entered '1'	System	02 Dec 2020 16:17:33

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:32:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:37
User entered '28/Dec/2020 07:34'	System	28 Dec 2020 15:34:30

US3742330

Folder: SAE USA-US127-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:32:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:02:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 21:32:37
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 15:34:30