

US3742022 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:28:13

All time stamps listed in this document are displayed in GMT

US3742022

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

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[Participant ID](#)

US3742022

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

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US3742022

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3742022

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	38
Age Units	YEARS
Age (Derived)	38
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 16:58:23

Generated On: 10 Jun 2021 09:28:13

Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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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 16:58:23

Generated On: 10 Jun 2021 09:28:13

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	SEASONAL ALLERGIES
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)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	GENERALIZED ECZEMA
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	GENERALIZED ANXIETY DISORDER
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)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	ASTHMA [MILD]
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	HIP PAIN
Start date (dd MMM yyyy)	UN AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:47
Height (xxx.x)	64.5 in
Weight (xxx.x)	244.0 lb
BMI (xxx.x)	41.32190 kg/m <sup>2</sup>
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 16:58:23

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 16:58:23

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Date of assessment (dd MMM yyyy) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 16:58:23

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	19 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742022

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:23

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 144164

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 16:58:23

Generated On: 10 Jun 2021 09:28:13

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 16:58:23

Generated On: 10 Jun 2021 09:28:13

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)	19 AUG 2020
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:47
Temperature (xxx.x)	097.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	065 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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)	19 AUG 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 17:21
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 16:51 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 16:51

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 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	15:13 (24 HR)
Collection date and time (derived)	19 AUG 2020 15:13



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	19 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 17:25

PC Open Date & Time

19 AUG 2020 17:11

PC Close Date & Time

19 AUG 2020 19:41

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**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	19 AUG 2020 22:02
PC Open Date & Time	19 AUG 2020 20:36
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 15:40

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 16:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**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

96.8 °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

22 AUG 2020 20:31

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**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

96.8 °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

23 AUG 2020 20:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**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

97.2 °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

24 AUG 2020 19:05

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**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

19 AUG 2020 17:25

PC Open Date & Time

19 AUG 2020 17:11

PC Close Date & Time

19 AUG 2020 19:41

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**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

19 AUG 2020 22:03

PC Open Date & Time

19 AUG 2020 20:36

PC Close Date & Time

20 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**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

20 AUG 2020 15:40

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**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

21 AUG 2020 16:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**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

22 AUG 2020 20:32

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**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

23 AUG 2020 20:29

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**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

24 AUG 2020 19:05

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**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

25 AUG 2020 20:40

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**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 ☐

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 17:26
PC Open Date & Time	19 AUG 2020 17:11
PC Close Date & Time	19 AUG 2020 19:41

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**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 ☐

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 22:03
PC Open Date & Time	19 AUG 2020 20:36
PC Close Date & Time	20 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**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 ☒

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 15:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:03
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**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 ☒

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:32
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**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)

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US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:29
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:06
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

64 of 3292

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:41
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3742022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:55
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	072 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:31
Temperature (xxx.x)	98.5 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:01 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 14:01

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

US3742022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	13:09 (24 HR)
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Collection date and time (derived)	16 SEP 2020 13:09
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US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:13	16 SEP 2020 13:13
Nasopharyngeal Swab 2	No		



US3742022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 16 SEP 2020 14:32

PC Open Date & Time 16 SEP 2020 14:21

PC Close Date & Time 16 SEP 2020 16:51

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 16 SEP 2020 19:06

PC Open Date & Time 16 SEP 2020 17:46

PC Close Date & Time 17 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 03:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**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

18 SEP 2020 16:29

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

19 SEP 2020 21:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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**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

21 SEP 2020 03:57

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**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

96.8 °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

21 SEP 2020 20:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**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

97.2 °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

22 SEP 2020 20:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 14:33

PC Open Date & Time

16 SEP 2020 14:21

PC Close Date & Time

16 SEP 2020 16:51

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**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

16 SEP 2020 19:07

PC Open Date & Time

16 SEP 2020 17:46

PC Close Date & Time

17 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**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

18 SEP 2020 03:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**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

18 SEP 2020 16:29

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**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

21 SEP 2020 03:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 20:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**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 ☐

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:33
PC Open Date & Time	16 SEP 2020 14:21
PC Close Date & Time	16 SEP 2020 16:51

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**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 ☐

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 19:08
PC Open Date & Time	16 SEP 2020 17:46
PC Close Date & Time	17 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**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 ☒

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 03:45
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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)



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 16:29
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**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)

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US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:10
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 03:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:52
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**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 ☒



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:00
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3742022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:23

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

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) \_\_\_\_\_

US3742022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3742022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	14 OCT 2020 14:50

US3742022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:24

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

21 OCT 2020 15:04:42

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

27 OCT 2020 08:38:04

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 17:08:13
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 92
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	17 NOV 2020 17:51:17
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 NOV 2020 12:07:02
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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 <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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 NOV 2020 06:32:03
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

04 DEC 2020 09:52:27

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

12 DEC 2020 17:24:37

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 16:58:25
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

25 DEC 2020 06:54:33

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

04 JAN 2021 02:47:44

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

10 JAN 2021 01:00:51

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 19:47:05

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

22 JAN 2021 15:53:05

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

29 JAN 2021 15:15:44

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

06 FEB 2021 18:36:08

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

14 FEB 2021 17:44:23

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

20 FEB 2021 18:19:33

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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	26 FEB 2021 15:20:55
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

07 MAR 2021 10:28:49

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

14 MAR 2021 17:17:15

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

22 MAR 2021 16:22:47

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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

29 MAR 2021 03:23:49

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 18:33:26
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 07:07:41

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 11:33:19

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 12:21:39
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Date and time of submission

03 MAY 2021 12:01:42

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAY 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 NOV 2021 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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°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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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 <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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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°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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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°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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2022 23:59



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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 <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"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**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 ☐

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

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[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

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US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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



US3742022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

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

US3742022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:28:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 12:35:51

US3742022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742022

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

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) \_\_\_\_\_

US3742022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

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.*

US3742022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	17 MAR 2021 09:55

US3742022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 14:19:41

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 14:19:41

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3742022**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

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*

**US3742022**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Date of Contact	02 DEC 2020
Time of Contact	14:20
Date and Time of Contact (derived)	02 DEC 2020 14:20
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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"/>



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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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US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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"/>



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	01 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	02 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 type="checkbox"/>
Day 10	<input checked="" 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 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	03 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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 (11)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	96.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	05 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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 (13)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	06 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (13)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 (14)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (14)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 02 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	08 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (15)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	09 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 02 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 (17)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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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Form: Symptom Log (17)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 02 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 ☐

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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"/>



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 ☐

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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 02 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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 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 checked="" 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 02 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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	15 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

	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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 20 Apr 2021 16:56:41

Generated On: 10 Jun 2021 09:28:13

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"/>

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Date of Visit	02 DEC 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	02 DEC 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)	1

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 16:25:47

Generated On: 10 Jun 2021 09:28:13

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 DEC 2020
Day 5	Yes	06 DEC 2020
Day 7	Yes	08 DEC 2020
Day 9	Yes	10 DEC 2020
Day 14	Yes	15 DEC 2020
Day 21	Yes	22 DEC 2020
Day 28	Yes	29 DEC 2020

US3742022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 DEC 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

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 DEC 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	02 DEC 2020 14:20
Height (xxx.x)	64.0 in
Weight (xxx.x)	241.1 lb
Temperature (xxx.x)	098.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	090 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

02 DEC 2020

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

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US3742022

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 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 DEC 2020

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28



US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 DEC 2020
Time of assessment (00:00-23:59)	15:11 (24 HR)
Vital Signs Date and Time (derived)	29 DEC 2020 15:11
Height (xxx.x)	65.0 in
Weight (xxx.x)	245.1 lb
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED- NEED INFO
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 DEC 2020

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

US3742022

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 16:25:46

Generated On: 10 Jun 2021 09:28:13

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 DEC 2020

US3742022

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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

Visit date (dd MMM yyyy)	20 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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US3742022

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:34:29

Generated On: 10 Jun 2021 09:28:13

Date of updated informed consent ( <i>dd MMM yyyy</i> )	20 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> )	20 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

US3742022

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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

US3742022

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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)	20 JAN 2021
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 07:42
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	098 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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)	20 JAN 2021
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 08:42
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	057 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	096 mmHg
Diastolic Blood Pressure units	MMHG



US3742022

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

20 JAN 2021

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

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US3742022

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 20 JAN 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3742022

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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) 20 JAN 2021

What was the treatment time? (00:00-23:59) 08:07 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 08:07

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

US3742022

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00-23:59)	07:32 (24 HR)
Collection date and time (derived)	20 JAN 2021 07:32

US3742022

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	07:36
Collection Date and Time (derived)	20 JAN 2021 07:36

US3742022

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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



US3742022

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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)	17 FEB 2021
Time of assessment (00:00-23:59)	08:00 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 08:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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)	17 FEB 2021
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 08:37
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	071 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG

US3742022

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3742022

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	17 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742022

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 08:06 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 08:06

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

What was the frequency of the study treatment dosing? ONCE

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

US3742022

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742022

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742022

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 20:55:44

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 20:55:45

Generated On: 10 Jun 2021 09:28:13

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) \_\_\_\_\_

US3742022

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 20:55:44

Generated On: 10 Jun 2021 09:28:13

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.*

US3742022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 20:55:44

Generated On: 10 Jun 2021 09:28:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

17 MAR 2021 09:55

US3742022

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

AEID	
Adverse event	LOWER BACK PAIN
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)	24 AUG 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)	24 AUG 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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EAB) (1725)

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US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

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:	
<hr/>	
Narrative	
<hr/>	
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)	



US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

AEID	
Adverse event	INJECTION SITE PAIN
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)	3 OCT 2020
Start time (00:00-23:59)	13:00 (24 HR)
AE start date and time (derived)	3 OCT 2020 13:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 OCT 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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EAB) (1725)

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US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

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)	_____

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

AEID	
Adverse event	LOOSE STOOL
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)	4 OCT 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)	4 OCT 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 (3)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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:	
<hr/>	
Narrative	
<hr/>	
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) 23 Feb 2021 16:25:44

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AEID

Adverse event

SINUS INFECTION

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)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Feb 2021 16:25:44

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AEID	
Adverse event	LOOSE STOOL
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)	18 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)	18 NOV 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 (5)

Data signed: (b) (4) 23 Feb 2021 16:25:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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:	
<hr/>	
Narrative	
<hr/>	
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 (6)

Data signed: (b) (4) 23 Feb 2021 16:25:44

Generated On: 10 Jun 2021 09:28:13

AEID	USA-US127-2020-MRNA-1273-P30 1000013
Adverse event	COVID 19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	24 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)	15 DEC 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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 16:25:44

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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	True
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 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	PARTICIPANT IS COVID-19 POSITIVE
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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Name of Medication ELURYNG

Prophylaxis Yes ☐  
No ☒

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify RING

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

If frequency is Other, specify EVERY THREE WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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Name of Medication FLUTICCASONE

Prophylaxis Yes ☐  
No ☒

Indication NASAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify SPRAYS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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)	UN UNK 2015	
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 (3)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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Name of Medication ADDERALL XR GENERIC

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFECIT  
DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 16:25:45

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Name of Medication CITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES/  
ASTHMA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication LEVOSALBUTAMOL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 45

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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Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication CLARITIN (GENERIC)

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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 (8)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication FLUOCINONIDE 0.05%  
SOLUTION

Prophylaxis Yes ☐  
No ☒

Indication ECZEMA

Dose per administration MORE THAN ONE

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

If dose unit is Other, specify DROPS

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 (8)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (9)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication FLUOCINONIDE 0.05  
%OINTMENT

Prophylaxis Yes ☐  
No ☒

Indication ECZEMA

Dose per administration 1

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

If dose unit is Other, specify DAB

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (10)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication DIAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED ANXIETY  
DISORDER

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 ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (11)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication WOMEN'S MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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 (12)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN 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 (13)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication FLAX SEED

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1400

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 (13)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (14)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 120

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) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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 (15)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication PROBIOTIC FOR WOMEN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (15)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (16)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (17)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication OXYMETAZOLINE HCL 0.05%

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (17)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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)		31 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)		02 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication SEASONAL FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS SEASONAL FLU  
VACCINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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)	03 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)		03 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"/>

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication HIP AND BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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 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"/>

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

Name of Medication DOXYCLINE

Prophylaxis Yes ☐  
No ☒

Indication SINUS INFECTION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Feb 2021 16:25:45

Generated On: 10 Jun 2021 09:28:13

	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)	24 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)	11 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"/>

US3742022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 20:55:44

Generated On: 10 Jun 2021 09:28:13

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3742022

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:28:13

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

US3742022

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:13

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 ☐



US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

SAEID	USA-US127-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

SAEID	USA-US127-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

SAEID	USA-US127-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/DEC/2020 16:05
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

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 16:25:48

Generated On: 10 Jun 2021 09:28:13

SAEID	USA-US127-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/JAN/2021 14:16
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

US3742022 (Prod: University of Maryland School of Medicine)

**US3742022**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:28:13**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'US3742022'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:41

US3742022

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	19 Aug 2020 19:58:08

US3742022

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:42



US3742022

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	19 Aug 2020 19:58:08

**US3742022**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'SCRN'	System	19 Aug 2020 19:58:08

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:43

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '38'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

**US3742022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:13**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'YEARS'	System	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '38'	System	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Female (F)'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00



US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'I'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00



US3742022

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	19 Aug 2020 19:59:00

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Aug 2020'	System	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2020'	System	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Amendment 2 (2)'	Hassan Haji (b) (4)	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	19 Aug 2020 20:03:27



US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	19 Aug 2020 20:03:27

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:54:42

US3742022

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'I'	System	19 Aug 2020 20:03:35

US3742022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	19 Aug 2020 20:03:35

US3742022

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:28:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:23:23

US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:26:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:26:16
Data point term sent to Coder	System	20 Aug 2020 12:25:25
User entered 'seasonal allergies'	Hassan Haji (b) (4)	20 Aug 2020 12:25:02

US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Sep 2020 17:51:55
User entered '30 Jun 2010'	(b) (4)	
	Hassan Haji (b) (4)	20 Aug 2020 12:25:02
	(b) (4)	

US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:25:02



US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:25:02

US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:25:02

US3742022

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:25:02

**US3742022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 2010'	System	08 Sep 2020 17:51:55
User entered 'Jun 2010'	System	20 Aug 2020 12:25:02

**US3742022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2010'	System	20 Aug 2020 12:25:02

**US3742022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:25:02

**US3742022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:25:02

US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Psychiatric disorders, HLGt: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:28:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:28:22
Data point term sent to Coder	System	20 Aug 2020 12:27:27
User entered 'attention deficit disorder'	Hassan Haji (b) (4)	20 Aug 2020 12:26:48



US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Sep 2020 17:52:11
User entered '30 Jun 2015'	(b) (4)	
	Hassan Haji (b) (4)	20 Aug 2020 12:26:48
	(b) (4)	

US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:26:48

**US3742022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:26:48

US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:26:48

US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:26:48

US3742022

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 2015'	System	08 Sep 2020 17:52:11
User entered 'Jun 2015'	System	20 Aug 2020 12:26:48

**US3742022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2015'	System	20 Aug 2020 12:26:48

**US3742022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:26:48



**US3742022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:26:48

US3742022

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:29:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:29:22
Data point term sent to Coder	System	20 Aug 2020 12:28:28
User entered 'depression'	Hassan Haji (b) (4)	20 Aug 2020 12:27:31

US3742022

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Sep 2020 17:52:28
User entered '30 Jun 2018'	(b) (4)	
	Hassan Haji (b) (4)	20 Aug 2020 12:27:31
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:27:31

**US3742022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:27:31

US3742022

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:27:31

US3742022

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:27:31

**US3742022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 2018'	System	08 Sep 2020 17:52:28
User entered 'Jun 2018'	System	20 Aug 2020 12:27:31



**US3742022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2018'	System	20 Aug 2020 12:27:31

US3742022

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:27:31

**US3742022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:27:31

US3742022

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:13:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:13:02
Data point term sent to Coder	System	23 Nov 2020 20:12:01
Coding entries removed.	Sherry McCammon (b) (4)	23 Nov 2020 20:11:21
User entered 'generalized ECZEMA' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 20:11:21
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:31:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:31:15
Data point term sent to Coder	System	20 Aug 2020 12:30:29
User entered 'eczema'	Hassan Haji (b) (4)	20 Aug 2020 12:29:33

US3742022

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Sep 2020 17:53:04
User entered '30 Jun 2010'	(b) (4)	
	Hassan Haji (b) (4)	20 Aug 2020 12:29:33
	(b) (4)	

US3742022

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:29:33

**US3742022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:29:33

US3742022

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:29:33



US3742022

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:29:33

**US3742022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 2010'	System	08 Sep 2020 17:53:04
User entered 'Jun 2010'	System	20 Aug 2020 12:29:33

**US3742022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2010'	System	20 Aug 2020 12:29:33

**US3742022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:29:33

**US3742022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:29:33

US3742022

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:31:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 12:31:15
Data point term sent to Coder	System	20 Aug 2020 12:30:30
User entered 'generalized anxiety disorder'	Hassan Haji (b) (4)	20 Aug 2020 12:30:18

US3742022

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	08 Sep 2020 17:53:20
User entered '30 Jun 2010'	(b) (4)	
	Hassan Haji (b) (4)	20 Aug 2020 12:30:18
	(b) (4)	

**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:30:18



**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:30:18

**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:30:18

US3742022

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:30:18

US3742022

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 2010'	System	08 Sep 2020 17:53:20
User entered 'Jun 2010'	System	20 Aug 2020 12:30:18

**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2010'	System	20 Aug 2020 12:30:18

**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:30:18

**US3742022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:30:18

US3742022

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 20:14:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 20:14:41
Data point term sent to Coder	System	23 Dec 2020 19:58:58
Coding entries removed.	Kaitlin Mason (b) (4)	23 Dec 2020 19:58:27
User entered 'ASTHMA [mild]' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Dec 2020 19:58:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:59:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:59:58
Data point term sent to Coder	System	30 Sep 2020 14:59:08
User entered 'ASTHMA'	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23



US3742022

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 1989'	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 1989'	System	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '1989'	System	30 Sep 2020 14:58:23

**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	30 Sep 2020 14:58:23



**US3742022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	30 Sep 2020 14:58:23

US3742022

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:12
Data point term sent to Coder	System	23 Nov 2020 20:06:41
User entered 'hip pain'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

**US3742022**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN Aug 2020'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

US3742022

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

**US3742022**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

US3742022

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

US3742022

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:14

US3742022

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Aug 2020'	System	23 Nov 2020 20:06:14



**US3742022**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2020'	System	23 Nov 2020 20:06:14

**US3742022**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:14

**US3742022**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:14

US3742022

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:10
Data point term sent to Coder	System	23 Nov 2020 20:06:40
User entered 'back pain'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36

US3742022

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN Aug 2020'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36

US3742022

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36



US3742022

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Aug 2020'	System	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '2020'	System	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:36

**US3742022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:36

US3742022

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:10:21
Data point term sent to Coder	System	23 Nov 2020 20:07:44
User entered 'endometriosis'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57

US3742022

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'UN UNK 1997'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57

US3742022

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57



**US3742022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57

**US3742022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57

US3742022

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 20:06:57

**US3742022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'Jan 1997'	System	23 Nov 2020 20:06:57

**US3742022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '1997'	System	23 Nov 2020 20:06:57

US3742022

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:57

**US3742022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Nov 2020 20:06:57

US3742022

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
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 20:12:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 20:12:49
Data point term sent to Coder	System	23 Dec 2020 19:56:55
User entered 'obesity'	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07



**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'I'	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Kaitlin Mason (b) (4)	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Dec 2020 19:56:07

**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Dec 2020 19:56:07



**US3742022**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	23 Dec 2020 19:56:07

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14:47'	Hassan Haji (b) (4)	20 Aug 2020 12:36:08

**US3742022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '19 Aug 2020 14:47'	System	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '64.5' in	(b) (4) Hassan Haji (b) (4)	20 Aug 2020 12:36:08
DataPoint set to visible.	(b) (4) System	19 Aug 2020 20:03:35

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '244.0' lb	Hassan Haji (b) (4)	20 Aug 2020 12:36:08
DataPoint set to visible.	System	19 Aug 2020 20:03:35

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
Amendment Manager: User entered '41.32190'	System	17 Sep 2020 00:14:31
User entered '41.3'	System	20 Aug 2020 12:36:08
DataPoint set to visible.	System	19 Aug 2020 20:03:35



US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'kg/m2'	System	20 Aug 2020 12:36:08
DataPoint set to visible.	System	19 Aug 2020 20:03:35

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:16:38
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'entered in day 1 to avoid duplication ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:38:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:38:32
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:29:19
User entered '097.1' F	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 12:38:32
User entered 'Other (Other)'	Hassan Haji (b) (4)	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 12:38:32
User entered 'temporal'	Hassan Haji (b) (4)	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 12:38:32
User entered '065'	Kaitlin Mason (b) (4)	20 Aug 2020 12:36:08
	(b) (4)	

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'bpm'	System	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 12:38:32
User entered '16'	Kaitlin Mason (b) (4)	20 Aug 2020 12:36:08
	(b) (4)	

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'breaths/min'	System	20 Aug 2020 12:36:08



US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 12:38:32
User entered '150'	Kaitlin Mason (b) (4)	20 Aug 2020 12:36:08
	(b) (4)	

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 12:38:32
User entered '085'	Kaitlin Mason (b) (4)	20 Aug 2020 12:36:08
	(b) (4)	

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	20 Aug 2020 12:36:08

US3742022

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58

US3742022

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:36:20

US3742022

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:01:10
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 18:03:11
User entered '19 Aug 2020'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:36:20



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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:39:04

US3742022

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:13

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:39:04



US3742022

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

US3742022

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

**US3742022**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

**US3742022**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

US3742022

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

**US3742022**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

**US3742022**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:48:43

**US3742022**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	20 Aug 2020 12:48:43



US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05



US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'I'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05



US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '0'	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 12:50:05

US3742022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:31

US3742022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:50:31

US3742022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	20 Aug 2020 12:50:31



US3742022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'VISIT1'	System	20 Aug 2020 12:50:31

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:54:10

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:38:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:38:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 19:54:10
User entered '144164' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:54:10

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:54:10

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM: Response noted, however Asthma is present on the Medical History page as Ongoing. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:47:41
Query 'Per CDM: Response noted, however Asthma is present on the Medical History page as Ongoing. Please review and update accordingly. ' answered with 'asthma is mild' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	23 Dec 2020 19:57:41
User opened query 'Per CDM: Response noted, however Asthma is present on the Medical History page as Ongoing. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 18:38:57
User closed query 'per CDM: asthma listed on medical history, please clarify severity and update as needed' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 18:38:57
Query 'per CDM: asthma listed on medical history, please clarify severity and update as needed' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	22 Dec 2020 20:09:04
User opened query 'per CDM: asthma listed on medical history, please clarify severity and update as needed' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:08:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:51:27

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:51:27

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM: Response noted, however no Medical History Condition has been added to match this Severe Obesity indication. Please review and update accordingly.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:47:47
' (Site from DM). Query 'Per CDM: Response noted, however no Medical History Condition has been added to match this Severe Obesity indication. Please review and update accordingly.	Kaitlin Mason (b) (4) (b) (4)	23 Dec 2020 19:57:48
' answered with 'updated' (Site from DM). User opened query 'Per CDM: Response noted, however no Medical History Condition has been added to match this Severe Obesity indication. Please review and update accordingly.	(b) (4), (b) (6)	23 Dec 2020 18:10:57
' (Site from DM). User closed query 'per CDM: obesity marked as yes but not recorded on medical history, please clarify or reconcile' (Site from DM). Query 'per CDM: obesity marked as yes but not recorded on medical history, please clarify or reconcile' answered with 'updated' (Site from DM). User opened query 'per CDM: obesity marked as yes but not recorded on medical history, please clarify or reconcile' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Kaitlin Mason (b) (4) (b) (4) (b) (4), (b) (6) Hassan Haji (b) (4) (b) (4)	23 Dec 2020 18:10:57 22 Dec 2020 20:09:09 22 Dec 2020 16:08:41 20 Aug 2020 12:51:27

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:51:27



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 12:51:27

US3742022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:13

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:00:41
Query 'per CDM: please input yes or no for this field' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	21 Dec 2020 20:32:40
User entered 'No (N)'	(b) (4) Kaitlin Mason (b) (4)	21 Dec 2020 20:32:33
User opened query 'per CDM: please input yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:58:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:35

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:25:45
Query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:17:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:17:39
User opened query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'entered in screening to avoid duplication' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:28
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:29:26
User entered '64.5' in	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:17:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15
User entered '244.0' lb	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:25:45
Query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:17:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:17:39
User opened query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'entered in screening to avoid duplication' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:28
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:29:26
User entered '64.5' in	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:17:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15
User entered '244.0' lb	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30



US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14:47'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '19 Aug 2020 14:47'	System	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '097.1' F	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Other (Other)'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'temporal'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30



US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '065'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'bpm'	System	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'breaths/min'	System	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '150'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '085'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	20 Aug 2020 12:57:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:25:45
Query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:17:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:17:39
User opened query 'Per CDM RQ: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:32:04
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'entered in screening to avoid duplication' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:28
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:29:26
User entered '64.5' in	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:17:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:37:15
User entered '244.0' lb	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:38:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol it is 30 min' (Site from System).	Hassan Haji (b) (4)	20 Aug 2020 12:58:52
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	20 Aug 2020 12:57:30
User entered '17:21'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '19 Aug 2020 17:21'	System	20 Aug 2020 12:57:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '98.4' F reason for change: New Information	System	20 Aug 2020 13:16:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Hassan Haji (b) (4)	20 Aug 2020 13:16:58
User entered '98.4' (non-conformant).	(b) (4)	
	System	20 Aug 2020 12:57:30
	Hassan Haji (b) (4)	20 Aug 2020 12:57:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Other (Other)'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'forehead'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '055'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'bpm'	System	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'breaths/min'	System	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:06
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Participant with post-vaccination systolic blood pressure of 158, not clinically significant as participant was asymptomatic and pre-vaccination systolic pressure was 150.' (Site from System).	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:16:50
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Aug 2020 12:57:30
User entered '158'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 12:57:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '085'	Hassan Haji (b) (4)	20 Aug 2020 12:57:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	20 Aug 2020 12:57:30

US3742022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:16:45
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' answered with 'entered in screening to avoid duplication' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:36:52
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 12:36:41
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:29:39
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:17:19

US3742022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 12:36:41
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 13:17:19

US3742022

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 11:50:02
Query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'UPDATED TO REMOVE DUPLICATE ENTRY' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:34:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:33:55
User opened query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:45:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:18:06

US3742022

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:33:55
User entered '19 Aug 2020'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:18:06

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:33:55
User entered 'Urine (URINE)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:18:06



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:33:55
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:18:06

US3742022

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:03:08
Query 'per CDM: please input yes or no in this field' answered with 'NOT COLLECTED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:08:32
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:08:25
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 13:44:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 19:33:55
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:18:06

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 13:18:06

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 13:18:06

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	20 Aug 2020 13:18:06

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Toni Robinson (b) (4)	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Toni Robinson (b) (4)	19 Aug 2020 20:54:01

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Toni Robinson (b) (4)	19 Aug 2020 20:54:01



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Toni Robinson (b) (4)	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16:51'	Toni Robinson (b) (4)	19 Aug 2020 20:54:01

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '19 Aug 2020 16:51'	System	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'ONCE'	System	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:54:01

US3742022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 13:18:50



US3742022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 13:18:50

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '15:13'	Hassan Haji (b) (4)	20 Aug 2020 13:18:50

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '19 Aug 2020 15:13'	System	20 Aug 2020 13:18:50

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '19 Aug 2020'	Hassan Haji (b) (4)	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '15:20'	Hassan Haji (b) (4)	20 Aug 2020 13:20:06

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '19 Aug 2020 15:20'	System	20 Aug 2020 13:20:06



US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	20 Aug 2020 13:20:06

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	20 Aug 2020 13:20:06

US3742022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Aug 2020 13:20:13

**US3742022**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	20 Aug 2020 13:20:13

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:24:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7be3c88a-a4c4-4dce-85c8-fa9c0318ae99'	System	19 Aug 2020 21:25:10
User entered 'Yes (Y)'	System	19 Aug 2020 21:25:10



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:24:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7be3c88a-a4c4-4dce-85c8-fa9c0318ae99'	System	19 Aug 2020 21:25:10
User entered '98.4'	System	19 Aug 2020 21:25:10

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7be3c88a-a4c4-4dce-85c8-fa9c0318ae99'	System	19 Aug 2020 21:25:10
User entered 'No (N)'	System	19 Aug 2020 21:25:10

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:07', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7be3c88a-a4c4-4dce-85c8-fa9c0318ae99'	System	19 Aug 2020 21:25:10
User entered '19 Aug 2020 17:25'	System	19 Aug 2020 21:25:10

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 17:11'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 19:41'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:02:29', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7255ede7-dd12-49a5-8c75-16bd53cdc3f8'	System	20 Aug 2020 02:02:57
User entered 'Yes (Y)'	System	20 Aug 2020 02:02:57

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:02:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7255ede7-dd12-49a5-8c75-16bd53cdc3f8'	System	20 Aug 2020 02:02:57
User entered '97.6'	System	20 Aug 2020 02:02:57



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:02:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7255ede7-dd12-49a5-8c75-16bd53cdc3f8'	System	20 Aug 2020 02:02:57
User entered 'No (N)'	System	20 Aug 2020 02:02:57

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:02:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7255ede7-dd12-49a5-8c75-16bd53cdc3f8'	System	20 Aug 2020 02:02:57
User entered '19 Aug 2020 22:02'	System	20 Aug 2020 02:02:57

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 20:36'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 2'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:40:15', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a605343d-74e9-495e-8072-9da083884c7d'	System	20 Aug 2020 19:40:50
User entered 'Yes (Y)'	System	20 Aug 2020 19:40:50

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:40:27', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a605343d-74e9-495e-8072-9da083884c7d' User entered '97.8'	System	20 Aug 2020 19:40:50
	System	20 Aug 2020 19:40:50

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:40:32', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a605343d-74e9-495e-8072-9da083884c7d'	System	20 Aug 2020 19:40:50
User entered 'No (N)'	System	20 Aug 2020 19:40:50



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:40:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a605343d-74e9-495e-8072-9da083884c7d'	System	20 Aug 2020 19:40:50
User entered '20 Aug 2020 15:40'	System	20 Aug 2020 19:40:50

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 3'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:02:27', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '560f2771-47e8-4d2c-afc2-f5f243696b9d'	System	21 Aug 2020 20:02:46
User entered 'Yes (Y)'	System	21 Aug 2020 20:02:46

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:02:36', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '560f2771-47e8-4d2c-afc2-f5f243696b9d'	System	21 Aug 2020 20:02:46
User entered '97.4'	System	21 Aug 2020 20:02:46

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:02:39', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '560f2771-47e8-4d2c-afc2-f5f243696b9d'	System	21 Aug 2020 20:02:46
User entered 'No (N)'	System	21 Aug 2020 20:02:46

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:02:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '560f2771-47e8-4d2c-afc2-f5f243696b9d'	System	21 Aug 2020 20:02:46
User entered '21 Aug 2020 16:02'	System	21 Aug 2020 20:02:46



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 4'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1e71e5e2-ff76-4d0a-8c6f-652869a41da3'	System	23 Aug 2020 00:31:51
User entered 'Yes (Y)'	System	23 Aug 2020 00:31:51

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:32', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1e71e5e2-ff76-4d0a-8c6f-652869a41da3'	System	23 Aug 2020 00:31:51
User entered '96.8'	System	23 Aug 2020 00:31:51

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:35', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1e71e5e2-ff76-4d0a-8c6f-652869a41da3'	System	23 Aug 2020 00:31:51
User entered 'No (N)'	System	23 Aug 2020 00:31:51

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1e71e5e2-ff76-4d0a-8c6f-652869a41da3'	System	23 Aug 2020 00:31:51
User entered '22 Aug 2020 20:31'	System	23 Aug 2020 00:31:51

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:54:01



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 5'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4e1c03c1-6de0-4598-bb71-025a58ef935c'	System	24 Aug 2020 00:28:24
User entered 'Yes (Y)'	System	24 Aug 2020 00:28:24

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:09', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4e1c03c1-6de0-4598-bb71-025a58ef935c'	System	24 Aug 2020 00:28:24
User entered '96.8'	System	24 Aug 2020 00:28:24

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:14', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4e1c03c1-6de0-4598-bb71-025a58ef935c'	System	24 Aug 2020 00:28:24
User entered 'No (N)'	System	24 Aug 2020 00:28:24

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4e1c03c1-6de0-4598-bb71-025a58ef935c'	System	24 Aug 2020 00:28:24
User entered '23 Aug 2020 20:28'	System	24 Aug 2020 00:28:24

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:54:01



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 6'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a752562e-fe5f-4741-943a-80706a635252'	System	24 Aug 2020 23:05:44
User entered 'Yes (Y)'	System	24 Aug 2020 23:05:44

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a752562e-fe5f-4741-943a-80706a635252'	System	24 Aug 2020 23:05:44
User entered '97.2'	System	24 Aug 2020 23:05:44

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a752562e-fe5f-4741-943a-80706a635252'	System	24 Aug 2020 23:05:44
User entered 'No (N)'	System	24 Aug 2020 23:05:44

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:40', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a752562e-fe5f-4741-943a-80706a635252'	System	24 Aug 2020 23:05:44
User entered '24 Aug 2020 19:05'	System	24 Aug 2020 23:05:44

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 7'	System	19 Aug 2020 20:54:01



US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:42:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cbbb5aa4-ac78-4538-b34d-78d704d78261'	System	26 Aug 2020 00:42:26
User entered 'Yes (Y)'	System	26 Aug 2020 00:42:26

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:42:14', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cbbb5aa4-ac78-4538-b34d-78d704d78261'	System	26 Aug 2020 00:42:26
User entered '96.8'	System	26 Aug 2020 00:42:26

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:42:16', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cbbb5aa4-ac78-4538-b34d-78d704d78261'	System	26 Aug 2020 00:42:26
User entered 'No (N)'	System	26 Aug 2020 00:42:26

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:42:22', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cbbb5aa4-ac78-4538-b34d-78d704d78261'	System	26 Aug 2020 00:42:26
User entered '25 Aug 2020 20:42'	System	26 Aug 2020 00:42:26

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'feffa3b-598f-4e58-8afe-f9aed09af3f3'	System	19 Aug 2020 21:26:02
User entered 'None (1)'	System	19 Aug 2020 21:26:02



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:39', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'feffa3b-598f-4e58-8afe-f9aed09af3f3'	System	19 Aug 2020 21:26:02
User entered 'No (N)'	System	19 Aug 2020 21:26:02

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'feffa3b-598f-4e58-8afe-f9aed09af3f3'	System	19 Aug 2020 21:26:02
User entered 'No (N)'	System	19 Aug 2020 21:26:02

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'feffa3b-598f-4e58-8afe-f9aed09af3f3'	System	19 Aug 2020 21:26:02
User entered 'None (1)'	System	19 Aug 2020 21:26:02

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:25:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'feffa3b-598f-4e58-8afe-f9aed09af3f3'	System	19 Aug 2020 21:26:02
User entered '19 Aug 2020 17:25'	System	19 Aug 2020 21:26:02

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 17:11'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 19:41'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:02:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c0d5207a-1a4e-4432-a15e-22a2bc9f4ebb'	System	20 Aug 2020 02:03:19
User entered 'None (1)'	System	20 Aug 2020 02:03:19



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c0d5207a-1a4e-4432-a15e-22a2bc9f4ebb'	System	20 Aug 2020 02:03:19
User entered 'No (N)'	System	20 Aug 2020 02:03:19

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c0d5207a-1a4e-4432-a15e-22a2bc9f4ebb'	System	20 Aug 2020 02:03:19
User entered 'No (N)'	System	20 Aug 2020 02:03:19

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c0d5207a-1a4e-4432-a15e-22a2bc9f4ebb'	System	20 Aug 2020 02:03:19
User entered 'None (1)'	System	20 Aug 2020 02:03:19

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c0d5207a-1a4e-4432-a15e-22a2bc9f4ebb'	System	20 Aug 2020 02:03:19
User entered '19 Aug 2020 22:03'	System	20 Aug 2020 02:03:19

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 20:36'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 2'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8d5c645b-5a44-48e8-adc4-732f50fd0e74'	System	20 Aug 2020 19:40:07
User entered 'None (1)'	System	20 Aug 2020 19:40:07



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8d5c645b-5a44-48e8-adc4-732f50fd0e74'	System	20 Aug 2020 19:40:07
User entered 'No (N)'	System	20 Aug 2020 19:40:07

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8d5c645b-5a44-48e8-adc4-732f50fd0e74'	System	20 Aug 2020 19:40:07
User entered 'No (N)'	System	20 Aug 2020 19:40:07

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8d5c645b-5a44-48e8-adc4-732f50fd0e74'	System	20 Aug 2020 19:40:07
User entered 'None (1)'	System	20 Aug 2020 19:40:07

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:40:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8d5c645b-5a44-48e8-adc4-732f50fd0e74'	System	20 Aug 2020 19:40:07
User entered '20 Aug 2020 15:40'	System	20 Aug 2020 19:40:07

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 3'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:02:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3101ff7-fd81-4171-a773-d024467188ff'	System	21 Aug 2020 20:03:21
User entered 'None (1)'	System	21 Aug 2020 20:03:21



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:07', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3101ff7-fd81-4171-a773-d024467188ff'	System	21 Aug 2020 20:03:21
User entered 'No (N)'	System	21 Aug 2020 20:03:21

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:12', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3101ff7-fd81-4171-a773-d024467188ff'	System	21 Aug 2020 20:03:21
User entered 'No (N)'	System	21 Aug 2020 20:03:21

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:15', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3101ff7-fd81-4171-a773-d024467188ff'	System	21 Aug 2020 20:03:21
User entered 'None (1)'	System	21 Aug 2020 20:03:21

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3101ff7-fd81-4171-a773-d024467188ff'	System	21 Aug 2020 20:03:21
User entered '21 Aug 2020 16:03'	System	21 Aug 2020 20:03:21

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 4'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f6e7e6fc-360e-4ce7-9e70-0fe57c6d1d08'	System	23 Aug 2020 00:32:05
User entered 'None (1)'	System	23 Aug 2020 00:32:05



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f6e7e6fc-360e-4ce7-9e70-0fe57c6d1d08'	System	23 Aug 2020 00:32:05
User entered 'No (N)'	System	23 Aug 2020 00:32:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f6e7e6fc-360e-4ce7-9e70-0fe57c6d1d08'	System	23 Aug 2020 00:32:05
User entered 'No (N)'	System	23 Aug 2020 00:32:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:31:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f6e7e6fc-360e-4ce7-9e70-0fe57c6d1d08'	System	23 Aug 2020 00:32:05
User entered 'None (1)'	System	23 Aug 2020 00:32:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f6e7e6fc-360e-4ce7-9e70-0fe57c6d1d08'	System	23 Aug 2020 00:32:05
User entered '22 Aug 2020 20:32'	System	23 Aug 2020 00:32:05

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 5'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:46', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19476667-e1d5-4bed-9007-c99bbb10101a'	System	24 Aug 2020 00:29:05
User entered 'None (1)'	System	24 Aug 2020 00:29:05



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19476667-e1d5-4bed-9007-c99bbb10101a'	System	24 Aug 2020 00:29:05
User entered 'No (N)'	System	24 Aug 2020 00:29:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19476667-e1d5-4bed-9007-c99bbb10101a'	System	24 Aug 2020 00:29:05
User entered 'No (N)'	System	24 Aug 2020 00:29:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:28:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19476667-e1d5-4bed-9007-c99bbb10101a'	System	24 Aug 2020 00:29:05
User entered 'None (1)'	System	24 Aug 2020 00:29:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19476667-e1d5-4bed-9007-c99bbb10101a'	System	24 Aug 2020 00:29:05
User entered '23 Aug 2020 20:29'	System	24 Aug 2020 00:29:05

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 6'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '836c0c0a-9bd3-4bc4-bc7b-304be3744543'	System	24 Aug 2020 23:05:57
User entered 'None (1)'	System	24 Aug 2020 23:05:57



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '836c0c0a-9bd3-4bc4-bc7b-304be3744543'	System	24 Aug 2020 23:05:57
User entered 'No (N)'	System	24 Aug 2020 23:05:57

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '836c0c0a-9bd3-4bc4-bc7b-304be3744543'	System	24 Aug 2020 23:05:57
User entered 'No (N)'	System	24 Aug 2020 23:05:57

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:50', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '836c0c0a-9bd3-4bc4-bc7b-304be3744543'	System	24 Aug 2020 23:05:57
User entered 'None (1)'	System	24 Aug 2020 23:05:57

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '836c0c0a-9bd3-4bc4-bc7b-304be3744543'	System	24 Aug 2020 23:05:57
User entered '24 Aug 2020 19:05'	System	24 Aug 2020 23:05:57

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 7'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'eb6af40d-f1ba-4c60-8478-215f27cdcb2a'	System	26 Aug 2020 00:40:40
User entered 'None (1)'	System	26 Aug 2020 00:40:40



US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'eb6af40d-f1ba-4c60-8478-215f27cdcb2a'	System	26 Aug 2020 00:40:40
User entered 'No (N)'	System	26 Aug 2020 00:40:40

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:25', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'eb6af40d-f1ba-4c60-8478-215f27cdcb2a'	System	26 Aug 2020 00:40:40
User entered 'No (N)'	System	26 Aug 2020 00:40:40

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'eb6af40d-f1ba-4c60-8478-215f27cdcb2a'	System	26 Aug 2020 00:40:40
User entered 'None (1)'	System	26 Aug 2020 00:40:40

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'eb6af40d-f1ba-4c60-8478-215f27cdcb2a'	System	26 Aug 2020 00:40:40
User entered '25 Aug 2020 20:40'	System	26 Aug 2020 00:40:40

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:05', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:16', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'None (0)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered 'No (N)'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T17:26:29', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42880a4f-446a-40a4-b6fe-7951ebdc42e6'	System	19 Aug 2020 21:26:34
User entered '19 Aug 2020 17:26'	System	19 Aug 2020 21:26:34

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 17:11'	System	19 Aug 2020 20:54:01



**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 19:41'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:22', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:31', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:36', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'None (0)'	System	20 Aug 2020 02:03:53



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:44', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered 'No (N)'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-19T22:03:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c892aa3c-f85d-4ccc-88cd-830199dba7c8'	System	20 Aug 2020 02:03:53
User entered '19 Aug 2020 22:03'	System	20 Aug 2020 02:03:53

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Aug 2020 20:36'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 2'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:31', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:34', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:39', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:38:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'None (0)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered 'No (N)'	System	20 Aug 2020 19:39:15

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-20T15:39:11', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'ff85c9d2-e3e4-419f-962c-efdda770c82c'	System	20 Aug 2020 19:39:15
User entered '20 Aug 2020 15:39'	System	20 Aug 2020 19:39:15

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 3'	System	19 Aug 2020 20:54:01



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:30', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:41', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'None (0)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered 'No (N)'	System	21 Aug 2020 20:04:02

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-21T16:03:57', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '020db5eb-d868-4e7c-8597-0383d32929d4'	System	21 Aug 2020 20:04:02
User entered '21 Aug 2020 16:03'	System	21 Aug 2020 20:04:02



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 4'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:09', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:12', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:14', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:16', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:20', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'None (0)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered 'No (N)'	System	23 Aug 2020 00:32:33

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-22T20:32:30', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a23b3705-fa5e-48ad-9f8c-5d2bd815633b'	System	23 Aug 2020 00:32:33
User entered '22 Aug 2020 20:32'	System	23 Aug 2020 00:32:33

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 5'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:07', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:12', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:15', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'None (0)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:25', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered 'No (N)'	System	24 Aug 2020 00:29:35

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-23T20:29:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '985050b4-797c-4240-b6c3-2a08adffef95'	System	24 Aug 2020 00:29:35
User entered '23 Aug 2020 20:29'	System	24 Aug 2020 00:29:35

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:54:01



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 6'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:05:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:04', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'None (0)'	System	24 Aug 2020 23:06:13

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered 'No (N)'	System	24 Aug 2020 23:06:13



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-24T19:06:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '46f88a19-8215-490a-95c4-a30adf6af0eb'	System	24 Aug 2020 23:06:13
User entered '24 Aug 2020 19:06'	System	24 Aug 2020 23:06:13

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 7'	System	19 Aug 2020 20:54:01

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:41', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09



US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:40:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'None (0)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:41:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered 'No (N)'	System	26 Aug 2020 00:41:09

US3742022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-08-25T20:41:04', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c56ccdfd-cca6-44ae-9806-f727811ae7b5'	System	26 Aug 2020 00:41:09
User entered '25 Aug 2020 20:41'	System	26 Aug 2020 00:41:09

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	26 Aug 2020 15:04:44

US3742022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '26 Aug 2020'	Faith Pa'ahana-Brown (b) (4)	26 Aug 2020 15:04:44



US3742022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	26 Aug 2020 15:04:44

US3742022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Faith Pa'ahana-Brown (b) (4)	26 Aug 2020 15:04:44

US3742022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	26 Aug 2020 15:04:50

**US3742022**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	26 Aug 2020 15:04:50

US3742022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	02 Sep 2020 16:50:23

US3742022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '2 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	02 Sep 2020 16:50:23

US3742022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	02 Sep 2020 16:50:23

US3742022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Faith Pa'ahana-Brown (b) (4)	02 Sep 2020 16:50:23



US3742022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	02 Sep 2020 16:50:29

**US3742022**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	02 Sep 2020 16:50:29

**US3742022**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 15:48:15

**US3742022**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '9 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 15:48:15

US3742022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 15:48:15

US3742022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 15:48:15

US3742022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 15:48:21

US3742022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	09 Sep 2020 15:48:21



US3742022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 18:03:11

US3742022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 18:03:11

US3742022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	16 Sep 2020 18:03:11

**US3742022**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'VISIT2'	System	16 Sep 2020 18:03:11

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '12:55'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43



US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '16 Sep 2020 12:55'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 14:58:05
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 14:58:05
User entered '98.8' F reason for change: Data Entry Error	Hassan Haji (b) (4)	17 Sep 2020 14:58:05
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 14:57:43
User entered '98.8' C	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '072'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'bpm'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'breaths/min'	System	17 Sep 2020 14:57:43



US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '136'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '083'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14:31'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43



US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '16 Sep 2020 14:31'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '98.5' F	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '060'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'bpm'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '15'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'breaths/min'	System	17 Sep 2020 14:57:43



US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '144'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '087'	Hassan Haji (b) (4)	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'mmHg'	System	17 Sep 2020 14:57:43

US3742022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 18:03:40

US3742022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 18:03:40

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	16 Sep 2020 18:04:19



US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

**US3742022**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

US3742022

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	16 Sep 2020 18:04:19

**US3742022**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	16 Sep 2020 18:04:19

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Toni Robinson (b) (4)	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Toni Robinson (b) (4)	16 Sep 2020 18:08:01



US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Toni Robinson (b) (4)	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Toni Robinson (b) (4)	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14:01'	Toni Robinson (b) (4)	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '16 Sep 2020 14:01'	System	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Left Arm (LEFT ARM)'	Toni Robinson (b) (4)	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'ONCE'	System	16 Sep 2020 18:08:01

US3742022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 18:08:01



US3742022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 14:59:17

US3742022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 14:59:17

US3742022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '13:09'	Hassan Haji (b) (4)	17 Sep 2020 14:59:17

US3742022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '16 Sep 2020 13:09'	System	17 Sep 2020 14:59:17

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '16 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '13:13'	Hassan Haji (b) (4)	17 Sep 2020 14:59:32



**US3742022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '16 Sep 2020 13:13'	System	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 14:59:32

**US3742022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	17 Sep 2020 14:59:32

US3742022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 14:59:51

US3742022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	17 Sep 2020 14:59:51

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:31:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '72247715-2c93-4006-8c0b-bd0a65c35d29'	System	16 Sep 2020 18:32:37
User entered 'Yes (Y)'	System	16 Sep 2020 18:32:37

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '72247715-2c93-4006-8c0b-bd0a65c35d29'	System	16 Sep 2020 18:32:37
User entered '98.5'	System	16 Sep 2020 18:32:37

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:30', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '72247715-2c93-4006-8c0b-bd0a65c35d29'	System	16 Sep 2020 18:32:37
User entered 'No (N)'	System	16 Sep 2020 18:32:37

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '72247715-2c93-4006-8c0b-bd0a65c35d29'	System	16 Sep 2020 18:32:37
User entered '16 Sep 2020 14:32'	System	16 Sep 2020 18:32:37

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 16:51'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:06:16', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e5b65e9c-21eb-4797-9947-51faf8eb8483'	System	16 Sep 2020 23:06:30
User entered 'Yes (Y)'	System	16 Sep 2020 23:06:30



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:06:20', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e5b65e9c-21eb-4797-9947-51faf8eb8483' User entered '97.7'	System	16 Sep 2020 23:06:30
	System	16 Sep 2020 23:06:30

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:06:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e5b65e9c-21eb-4797-9947-51faf8eb8483'	System	16 Sep 2020 23:06:30
User entered 'No (N)'	System	16 Sep 2020 23:06:30

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:06:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e5b65e9c-21eb-4797-9947-51faf8eb8483'	System	16 Sep 2020 23:06:30
User entered '16 Sep 2020 19:06'	System	16 Sep 2020 23:06:30

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 17:46'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 2'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7a675cfb-692e-4fb2-8ac2-47f142be9e45'	System	18 Sep 2020 07:44:26
User entered 'Yes (Y)'	System	18 Sep 2020 07:44:26

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7a675cfb-692e-4fb2-8ac2-47f142be9e45'	System	18 Sep 2020 07:44:26
User entered '98.3'	System	18 Sep 2020 07:44:26



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:16', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7a675cfb-692e-4fb2-8ac2-47f142be9e45'	System	18 Sep 2020 07:44:26
User entered 'No (N)'	System	18 Sep 2020 07:44:26

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7a675cfb-692e-4fb2-8ac2-47f142be9e45'	System	18 Sep 2020 07:44:26
User entered '18 Sep 2020 03:44'	System	18 Sep 2020 07:44:26

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 3'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:28:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '084178f3-c52b-4760-80ab-e1a183c8aa70'	System	18 Sep 2020 20:29:17
User entered 'Yes (Y)'	System	18 Sep 2020 20:29:17

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:28:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '084178f3-c52b-4760-80ab-e1a183c8aa70'	System	18 Sep 2020 20:29:17
User entered '97.1'	System	18 Sep 2020 20:29:17

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:07', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '084178f3-c52b-4760-80ab-e1a183c8aa70'	System	18 Sep 2020 20:29:17
User entered 'No (N)'	System	18 Sep 2020 20:29:17



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '084178f3-c52b-4760-80ab-e1a183c8aa70'	System	18 Sep 2020 20:29:17
User entered '18 Sep 2020 16:29'	System	18 Sep 2020 20:29:17

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 4'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:08:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '91b86c87-65a1-4a6d-9c06-c700aa9db2ce'	System	20 Sep 2020 01:09:18
User entered 'Yes (Y)'	System	20 Sep 2020 01:09:18

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:08:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '91b86c87-65a1-4a6d-9c06-c700aa9db2ce' User entered '98.1'	System	20 Sep 2020 01:09:18
	System	20 Sep 2020 01:09:18

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '91b86c87-65a1-4a6d-9c06-c700aa9db2ce'	System	20 Sep 2020 01:09:18
User entered 'No (N)'	System	20 Sep 2020 01:09:18

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '91b86c87-65a1-4a6d-9c06-c700aa9db2ce'	System	20 Sep 2020 01:09:18
User entered '19 Sep 2020 21:09'	System	20 Sep 2020 01:09:18



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 5'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:22', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0fd6413a-113b-45b9-a617-f683ed66b53b'	System	21 Sep 2020 07:57:57
User entered 'Yes (Y)'	System	21 Sep 2020 07:57:57

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0fd6413a-113b-45b9-a617-f683ed66b53b' User entered '97.9'	System	21 Sep 2020 07:57:57
	System	21 Sep 2020 07:57:57

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0fd6413a-113b-45b9-a617-f683ed66b53b'	System	21 Sep 2020 07:57:57
User entered 'No (N)'	System	21 Sep 2020 07:57:57

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0fd6413a-113b-45b9-a617-f683ed66b53b'	System	21 Sep 2020 07:57:57
User entered '21 Sep 2020 03:57'	System	21 Sep 2020 07:57:57

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 6'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:50:32', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f867b115-6ec6-4681-b679-b7c78a40ae01'	System	22 Sep 2020 00:51:22
User entered 'Yes (Y)'	System	22 Sep 2020 00:51:22

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:50:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f867b115-6ec6-4681-b679-b7c78a40ae01'	System	22 Sep 2020 00:51:22
User entered '96.8'	System	22 Sep 2020 00:51:22

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:14', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f867b115-6ec6-4681-b679-b7c78a40ae01'	System	22 Sep 2020 00:51:22
User entered 'No (N)'	System	22 Sep 2020 00:51:22

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'f867b115-6ec6-4681-b679-b7c78a40ae01'	System	22 Sep 2020 00:51:22
User entered '21 Sep 2020 20:51'	System	22 Sep 2020 00:51:22

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 7'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'b46e8a47-98e5-479f-89ad-c46b8435ab58'	System	23 Sep 2020 00:59:25
User entered 'Yes (Y)'	System	23 Sep 2020 00:59:25

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:11', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'b46e8a47-98e5-479f-89ad-c46b8435ab58'	System	23 Sep 2020 00:59:25
User entered '97.2'	System	23 Sep 2020 00:59:25

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'b46e8a47-98e5-479f-89ad-c46b8435ab58'	System	23 Sep 2020 00:59:25
User entered 'No (N)'	System	23 Sep 2020 00:59:25

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'b46e8a47-98e5-479f-89ad-c46b8435ab58'	System	23 Sep 2020 00:59:25
User entered '22 Sep 2020 20:59'	System	23 Sep 2020 00:59:25

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fba44ae4-7e8d-416e-83f6-2789a0021f07'	System	16 Sep 2020 18:33:13
User entered 'None (1)'	System	16 Sep 2020 18:33:13

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fba44ae4-7e8d-416e-83f6-2789a0021f07'	System	16 Sep 2020 18:33:13
User entered 'No (N)'	System	16 Sep 2020 18:33:13

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:32:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fba44ae4-7e8d-416e-83f6-2789a0021f07'	System	16 Sep 2020 18:33:13
User entered 'No (N)'	System	16 Sep 2020 18:33:13

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fba44ae4-7e8d-416e-83f6-2789a0021f07'	System	16 Sep 2020 18:33:13
User entered 'None (1)'	System	16 Sep 2020 18:33:13

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fba44ae4-7e8d-416e-83f6-2789a0021f07'	System	16 Sep 2020 18:33:13
User entered '16 Sep 2020 14:33'	System	16 Sep 2020 18:33:13

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 16:51'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:06:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0060eeb4-e9ce-47a7-8e8d-7a71075fd6b5'	System	16 Sep 2020 23:07:24
User entered 'None (1)'	System	16 Sep 2020 23:07:24

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:09', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0060eeb4-e9ce-47a7-8e8d-7a71075fd6b5'	System	16 Sep 2020 23:07:24
User entered 'No (N)'	System	16 Sep 2020 23:07:24

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:11', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0060eeb4-e9ce-47a7-8e8d-7a71075fd6b5'	System	16 Sep 2020 23:07:24
User entered 'No (N)'	System	16 Sep 2020 23:07:24

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0060eeb4-e9ce-47a7-8e8d-7a71075fd6b5'	System	16 Sep 2020 23:07:24
User entered 'None (1)'	System	16 Sep 2020 23:07:24

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:21', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0060eeb4-e9ce-47a7-8e8d-7a71075fd6b5'	System	16 Sep 2020 23:07:24
User entered '16 Sep 2020 19:07'	System	16 Sep 2020 23:07:24

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 17:46'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 2'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42cc68e2-b8f1-41c8-bb8f-67fe38a8f0ac'	System	18 Sep 2020 07:44:40
User entered 'None (1)'	System	18 Sep 2020 07:44:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42cc68e2-b8f1-41c8-bb8f-67fe38a8f0ac'	System	18 Sep 2020 07:44:40
User entered 'No (N)'	System	18 Sep 2020 07:44:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42cc68e2-b8f1-41c8-bb8f-67fe38a8f0ac'	System	18 Sep 2020 07:44:40
User entered 'No (N)'	System	18 Sep 2020 07:44:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:31', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42cc68e2-b8f1-41c8-bb8f-67fe38a8f0ac'	System	18 Sep 2020 07:44:40
User entered 'None (1)'	System	18 Sep 2020 07:44:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:34', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '42cc68e2-b8f1-41c8-bb8f-67fe38a8f0ac'	System	18 Sep 2020 07:44:40
User entered '18 Sep 2020 03:44'	System	18 Sep 2020 07:44:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 3'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:28', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6de795a6-6951-4502-b009-d9e07845a7fc'	System	18 Sep 2020 20:29:42
User entered 'None (1)'	System	18 Sep 2020 20:29:42

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:30', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6de795a6-6951-4502-b009-d9e07845a7fc'	System	18 Sep 2020 20:29:42
User entered 'No (N)'	System	18 Sep 2020 20:29:42

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:32', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6de795a6-6951-4502-b009-d9e07845a7fc'	System	18 Sep 2020 20:29:42
User entered 'No (N)'	System	18 Sep 2020 20:29:42

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:34', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6de795a6-6951-4502-b009-d9e07845a7fc'	System	18 Sep 2020 20:29:42
User entered 'None (1)'	System	18 Sep 2020 20:29:42

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:37', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6de795a6-6951-4502-b009-d9e07845a7fc'	System	18 Sep 2020 20:29:42
User entered '18 Sep 2020 16:29'	System	18 Sep 2020 20:29:42

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 4'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:22', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c2013ff7-69d1-4b28-b313-63a15b1e2b21'	System	20 Sep 2020 01:09:40
User entered 'None (1)'	System	20 Sep 2020 01:09:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c2013ff7-69d1-4b28-b313-63a15b1e2b21'	System	20 Sep 2020 01:09:40
User entered 'No (N)'	System	20 Sep 2020 01:09:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:25', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c2013ff7-69d1-4b28-b313-63a15b1e2b21'	System	20 Sep 2020 01:09:40
User entered 'No (N)'	System	20 Sep 2020 01:09:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c2013ff7-69d1-4b28-b313-63a15b1e2b21'	System	20 Sep 2020 01:09:40
User entered 'None (1)'	System	20 Sep 2020 01:09:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:36', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c2013ff7-69d1-4b28-b313-63a15b1e2b21'	System	20 Sep 2020 01:09:40
User entered '19 Sep 2020 21:09'	System	20 Sep 2020 01:09:40

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 5'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8be22013-cded-43aa-b063-a93c46181b22'	System	21 Sep 2020 07:56:56
User entered 'None (1)'	System	21 Sep 2020 07:56:56

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8be22013-cded-43aa-b063-a93c46181b22'	System	21 Sep 2020 07:56:56
User entered 'No (N)'	System	21 Sep 2020 07:56:56

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8be22013-cded-43aa-b063-a93c46181b22'	System	21 Sep 2020 07:56:56
User entered 'No (N)'	System	21 Sep 2020 07:56:56

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8be22013-cded-43aa-b063-a93c46181b22'	System	21 Sep 2020 07:56:56
User entered 'None (1)'	System	21 Sep 2020 07:56:56

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8be22013-cded-43aa-b063-a93c46181b22'	System	21 Sep 2020 07:56:56
User entered '21 Sep 2020 03:56'	System	21 Sep 2020 07:56:56

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 6'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:36', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6d9ade81-a824-4b53-999e-634c131a67a6'	System	22 Sep 2020 00:51:54
User entered 'None (1)'	System	22 Sep 2020 00:51:54

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6d9ade81-a824-4b53-999e-634c131a67a6'	System	22 Sep 2020 00:51:54
User entered 'No (N)'	System	22 Sep 2020 00:51:54

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:40', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6d9ade81-a824-4b53-999e-634c131a67a6'	System	22 Sep 2020 00:51:54
User entered 'No (N)'	System	22 Sep 2020 00:51:54

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6d9ade81-a824-4b53-999e-634c131a67a6'	System	22 Sep 2020 00:51:54
User entered 'None (1)'	System	22 Sep 2020 00:51:54

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6d9ade81-a824-4b53-999e-634c131a67a6'	System	22 Sep 2020 00:51:54
User entered '21 Sep 2020 20:51'	System	22 Sep 2020 00:51:54

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 7'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2438f4f2-691d-4281-bcdd-f71aa13c23c4'	System	23 Sep 2020 01:00:08
User entered 'None (1)'	System	23 Sep 2020 01:00:08

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2438f4f2-691d-4281-bcdd-f71aa13c23c4'	System	23 Sep 2020 01:00:08
User entered 'No (N)'	System	23 Sep 2020 01:00:08

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2438f4f2-691d-4281-bcdd-f71aa13c23c4'	System	23 Sep 2020 01:00:08
User entered 'No (N)'	System	23 Sep 2020 01:00:08

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:40', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2438f4f2-691d-4281-bcdd-f71aa13c23c4'	System	23 Sep 2020 01:00:08
User entered 'None (1)'	System	23 Sep 2020 01:00:08

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T20:59:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2438f4f2-691d-4281-bcdd-f71aa13c23c4'	System	23 Sep 2020 01:00:08
User entered '22 Sep 2020 20:59'	System	23 Sep 2020 01:00:08

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:36', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:41', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'None (0)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered 'No (N)'	System	16 Sep 2020 18:33:54

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T14:33:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '226a2faa-8316-4e80-977c-e79781caff7f'	System	16 Sep 2020 18:33:54
User entered '16 Sep 2020 14:33'	System	16 Sep 2020 18:33:54



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 18:08:01

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 16:51'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:57', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:07:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:08:04', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:08:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:08:10', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'None (0)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:08:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered 'No (N)'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-16T19:08:21', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'bd973531-77f7-4d57-a074-7141d509a246'	System	16 Sep 2020 23:08:26
User entered '16 Sep 2020 19:08'	System	16 Sep 2020 23:08:26

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '16 Sep 2020 17:46'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 2'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:46', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:50', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'None (0)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:44:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered 'No (N)'	System	18 Sep 2020 07:45:06

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T03:45:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '19b677d7-7102-42d0-97ba-4049477a0f1b'	System	18 Sep 2020 07:45:06
User entered '18 Sep 2020 03:45'	System	18 Sep 2020 07:45:06

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 3'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:43', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:45', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:47', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'None (0)'	System	18 Sep 2020 20:30:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered 'No (N)'	System	18 Sep 2020 20:30:08



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-18T16:29:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '87480bd4-6f2b-4f20-ae28-30c28ef8fe07'	System	18 Sep 2020 20:30:08
User entered '18 Sep 2020 16:29'	System	18 Sep 2020 20:30:08

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 4'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:55', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'None (0)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:09:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered 'No (N)'	System	20 Sep 2020 01:10:08

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-19T21:10:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '1ae897e8-2aea-4a6b-a965-0d2e62c8636a'	System	20 Sep 2020 01:10:08
User entered '19 Sep 2020 21:10'	System	20 Sep 2020 01:10:08

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 5'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:56:59', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'None (0)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered 'No (N)'	System	21 Sep 2020 07:57:16

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T03:57:11', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '702b733b-6fb6-4b89-90ae-4f4e07407c78'	System	21 Sep 2020 07:57:16
User entered '21 Sep 2020 03:57'	System	21 Sep 2020 07:57:16

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:08:01



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 6'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:52', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'None (0)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'None (0)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'None (0)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:51:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81' User entered 'None (0)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:52:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'None (0)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:52:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'None (0)'	System	22 Sep 2020 00:52:12



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:52:05', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered 'No (N)'	System	22 Sep 2020 00:52:12

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-21T20:52:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '0f325a06-45c3-4f66-be20-c17058334c81'	System	22 Sep 2020 00:52:12
User entered '21 Sep 2020 20:52'	System	22 Sep 2020 00:52:12

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

**US3742022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	16 Sep 2020 18:08:01
User entered 'Day 7'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:04', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:09', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33



US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:15', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'None (0)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:21', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered 'No (N)'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-09-22T21:00:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c3057446-1100-49a4-a8f5-6573bbd5beae'	System	23 Sep 2020 01:00:33
User entered '22 Sep 2020 21:00'	System	23 Sep 2020 01:00:33

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:08:01

US3742022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:08:01

**US3742022**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 17:42:31



**US3742022**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '23 Sep 2020'	Sherry McCammon (b) (4)	23 Sep 2020 17:42:31

US3742022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Sep 2020 17:42:31

US3742022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	23 Sep 2020 17:42:31

US3742022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 17:42:36

**US3742022**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	23 Sep 2020 17:42:36

**US3742022**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 14:55:44

US3742022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 14:55:44

US3742022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	30 Sep 2020 14:55:44



US3742022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 14:55:44

US3742022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 14:55:50

US3742022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	30 Sep 2020 14:55:50

US3742022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Oct 2020 19:42:56

US3742022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '7 Oct 2020'	Hassan Haji (b) (4)	07 Oct 2020 19:42:56

US3742022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	07 Oct 2020 19:42:56

**US3742022**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	07 Oct 2020 19:42:56

US3742022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Oct 2020 19:43:00



**US3742022**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	07 Oct 2020 19:43:00

US3742022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	15 Oct 2020 14:15:45

US3742022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14 Oct 2020'	Hassan Haji (b) (4)	15 Oct 2020 14:15:45

US3742022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	15 Oct 2020 14:15:45

**US3742022**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'VISIT3'	System	15 Oct 2020 14:15:45

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'No (N)'	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06



US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	15 Oct 2020 14:16:06



US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered empty.	System	15 Oct 2020 14:16:06

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19

US3742022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19

US3742022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	15 Oct 2020 14:16:19

US3742022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14 Oct 2020'	Hassan Haji (b) (4)	15 Oct 2020 14:16:19



US3742022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	15 Oct 2020 14:18:41

US3742022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered '14 Oct 2020'	Hassan Haji (b) (4)	15 Oct 2020 14:18:41

US3742022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 16:36:39
User entered '14:50' reason for change: Data Entry Error	System	20 Oct 2020 16:36:39
User opened query 'Data is required. Please provide.' (Site from System).	Kaitlin Mason (b) (4)	20 Oct 2020 16:36:39
User entered empty.	(b) (4)	15 Oct 2020 14:18:41
	Hassan Haji (b) (4)	15 Oct 2020 14:18:41
	(b) (4)	

US3742022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered '14 Oct 2020 14:50'	System	20 Oct 2020 16:36:39
User entered empty.	System	15 Oct 2020 14:18:41

US3742022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 16:58:24
User entered 'Yes (Y)'	Hassan Haji (b) (4)	15 Oct 2020 14:19:33

US3742022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	15 Oct 2020 14:19:33

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 64'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-21T15:04:34', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '64091a40-2df9-4056-b763-f99143ebaa6d'	System	21 Oct 2020 19:04:46
User entered 'No (N)'	System	21 Oct 2020 19:04:46



US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-21T15:04:37', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '64091a40-2df9-4056-b763-f99143ebaa6d'	System	21 Oct 2020 19:04:46
User entered 'No (N)'	System	21 Oct 2020 19:04:46

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-21T15:04:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '64091a40-2df9-4056-b763-f99143ebaa6d' User entered '21 Oct 2020 15:04:42'	System	21 Oct 2020 19:04:46
	System	21 Oct 2020 19:04:46

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 71'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-27T08:37:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2ef5f7b8-27c5-4739-8d21-8015cb729cc9'	System	27 Oct 2020 12:38:09
User entered 'No (N)'	System	27 Oct 2020 12:38:09

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-27T08:37:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2ef5f7b8-27c5-4739-8d21-8015cb729cc9'	System	27 Oct 2020 12:38:09
User entered 'No (N)'	System	27 Oct 2020 12:38:09

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-10-27T08:38:04', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2ef5f7b8-27c5-4739-8d21-8015cb729cc9' User entered '27 Oct 2020 08:38:04'	System	27 Oct 2020 12:38:09
	System	27 Oct 2020 12:38:09



**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 78'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-03T17:08:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '09369b98-3230-47d7-b5ce-316ac44925bb'	System	03 Nov 2020 22:08:20
User entered 'No (N)'	System	03 Nov 2020 22:08:20

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-03T17:08:09', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '09369b98-3230-47d7-b5ce-316ac44925bb'	System	03 Nov 2020 22:08:20
User entered 'No (N)'	System	03 Nov 2020 22:08:20

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-03T17:08:13', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '09369b98-3230-47d7-b5ce-316ac44925bb'	System	03 Nov 2020 22:08:20
User entered '03 Nov 2020 17:08:13'	System	03 Nov 2020 22:08:20

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:54:01



US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered 'Day 92'	System	19 Aug 2020 20:54:01

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-17T17:51:07', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'd167faab-d369-4dcc-a32a-bd16f20be486'	System	17 Nov 2020 22:51:20
User entered 'No (N)'	System	17 Nov 2020 22:51:20

US3742022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-17T17:51:11', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'd167faab-d369-4dcc-a32a-bd16f20be486'	System	17 Nov 2020 22:51:20
User entered 'No (N)'	System	17 Nov 2020 22:51:20

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-17T17:51:17', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'd167faab-d369-4dcc-a32a-bd16f20be486'	System	17 Nov 2020 22:51:20
User entered '17 Nov 2020 17:51:17'	System	17 Nov 2020 22:51:20

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:27:20
Data entry locked.	System	19 Aug 2020 20:54:01
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:54:01

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-20T12:06:35', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered 'Yes (Y)'	System	20 Nov 2020 17:07:14



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-11-20T12:06:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered 'No (N)'	System	20 Nov 2020 17:07:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-20T12:06:44', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered 'No (N)'	System	20 Nov 2020 17:07:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-20T12:06:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered 'Yes (Y)'	System	20 Nov 2020 17:07:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please 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 (8febb5081b9c711f)', Time: '2020-11-20T12:06:58', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 17:07:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-20T12:07:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'e8c2ba7e-35a4-4665-adbb-7e8e25128d76'	System	20 Nov 2020 17:07:14
User entered '20 Nov 2020 12:07:02'	System	20 Nov 2020 17:07:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-27T06:31:42', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered 'Yes (Y)'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-11-27T06:31:44', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered 'Yes (Y)'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Please 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 (8febb5081b9c711f)', Time: '2020-11-27T06:31:49', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-27T06:31:53', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered 'No (N)'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-11-27T06:32:01', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered 'No (N)'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-11-27T06:32:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '31920a92-7379-4dff-98d1-4c5a5b1ad934'	System	27 Nov 2020 11:32:14
User entered '27 Nov 2020 06:32:03'	System	27 Nov 2020 11:32:14

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-12-04T09:52:06', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8ee5a9de-cca0-4d12-bea3-3e25870f38c5'	System	04 Dec 2020 14:52:30
User entered 'No (N)'	System	04 Dec 2020 14:52:30

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-12-04T09:52:12', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8ee5a9de-cca0-4d12-bea3-3e25870f38c5'	System	04 Dec 2020 14:52:30
User entered 'No (N)'	System	04 Dec 2020 14:52:30

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-12-04T09:52:27', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8ee5a9de-cca0-4d12-bea3-3e25870f38c5'	System	04 Dec 2020 14:52:30
User entered '04 Dec 2020 09:52:27'	System	04 Dec 2020 14:52:30

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-12-12T17:24:29', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a42f13da-edf9-4463-a5aa-40e69ae226ae'	System	12 Dec 2020 22:24:40
User entered 'No (N)'	System	12 Dec 2020 22:24:40



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-12-12T17:24:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a42f13da-edf9-4463-a5aa-40e69ae226ae'	System	12 Dec 2020 22:24:40
User entered 'No (N)'	System	12 Dec 2020 22:24:40

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-12-12T17:24:37', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a42f13da-edf9-4463-a5aa-40e69ae226ae'	System	12 Dec 2020 22:24:40
User entered '12 Dec 2020 17:24:37'	System	12 Dec 2020 22:24:40

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-12-18T16:58:19', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cfe670cb-9479-49e3-b63e-ac17de0bf45b'	System	18 Dec 2020 21:58:28
User entered 'No (N)'	System	18 Dec 2020 21:58:28

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-12-18T16:58:22', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cfe670cb-9479-49e3-b63e-ac17de0bf45b'	System	18 Dec 2020 21:58:28
User entered 'No (N)'	System	18 Dec 2020 21:58:28

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-12-18T16:58:25', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'cfe670cb-9479-49e3-b63e-ac17de0bf45b' User entered '18 Dec 2020 16:58:25'	System	18 Dec 2020 21:58:28
	System	18 Dec 2020 21:58:28



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2020-12-25T06:54:24', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fbca7f63-a64c-4f14-a83c-11b995351589'	System	25 Dec 2020 11:54:38
User entered 'No (N)'	System	25 Dec 2020 11:54:38

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2020-12-25T06:54:27', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fbca7f63-a64c-4f14-a83c-11b995351589'	System	25 Dec 2020 11:54:38
User entered 'No (N)'	System	25 Dec 2020 11:54:38

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2020-12-25T06:54:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'fbca7f63-a64c-4f14-a83c-11b995351589' User entered '25 Dec 2020 06:54:33'	System	25 Dec 2020 11:54:38
	System	25 Dec 2020 11:54:38

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-01-04T02:47:38', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '16fab98b-7763-4aee-8c78-6c11060d5c1a'	System	04 Jan 2021 07:47:51
User entered 'No (N)'	System	04 Jan 2021 07:47:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-01-04T02:47:40', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '16fab98b-7763-4aee-8c78-6c11060d5c1a'	System	04 Jan 2021 07:47:51
User entered 'No (N)'	System	04 Jan 2021 07:47:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-01-04T02:47:44', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '16fab98b-7763-4aee-8c78-6c11060d5c1a' User entered '04 Jan 2021 02:47:44'	System	04 Jan 2021 07:47:51
	System	04 Jan 2021 07:47:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-01-10T01:00:46', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'aa4c19f9-c0bd-4d70-b491-d0d425b78f7d'	System	10 Jan 2021 06:00:57
User entered 'No (N)'	System	10 Jan 2021 06:00:57



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-01-10T01:00:48', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'aa4c19f9-c0bd-4d70-b491-d0d425b78f7d'	System	10 Jan 2021 06:00:57
User entered 'No (N)'	System	10 Jan 2021 06:00:57

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-01-10T01:00:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'aa4c19f9-c0bd-4d70-b491-d0d425b78f7d' User entered '10 Jan 2021 01:00:51'	System	10 Jan 2021 06:00:57

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-01-16T19:46:51', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4bcb31a4-0389-4f6d-a14f-da9d5695e46e'	System	17 Jan 2021 00:47:05
User entered 'No (N)'	System	17 Jan 2021 00:47:05

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-01-16T19:46:54', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4bcb31a4-0389-4f6d-a14f-da9d5695e46e'	System	17 Jan 2021 00:47:05
User entered 'No (N)'	System	17 Jan 2021 00:47:05

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-01-16T19:47:05', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4bcb31a4-0389-4f6d-a14f-da9d5695e46e'	System	17 Jan 2021 00:47:05
User entered '16 Jan 2021 19:47:05'	System	17 Jan 2021 00:47:05



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-01-22T15:52:56', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '641b484a-1ecb-4eb1-a3d4-9ee3aa764b2c'	System	22 Jan 2021 20:53:08
User entered 'No (N)'	System	22 Jan 2021 20:53:08

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-01-22T15:53:02', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '641b484a-1ecb-4eb1-a3d4-9ee3aa764b2c'	System	22 Jan 2021 20:53:08
User entered 'No (N)'	System	22 Jan 2021 20:53:08

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-01-22T15:53:05', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '641b484a-1ecb-4eb1-a3d4-9ee3aa764b2c'	System	22 Jan 2021 20:53:08
User entered '22 Jan 2021 15:53:05'	System	22 Jan 2021 20:53:08

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-01-29T15:15:39', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '75eaaeaa-7146-42ee-a8a3-205f986adf2c'	System	29 Jan 2021 20:15:49
User entered 'No (N)'	System	29 Jan 2021 20:15:49

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-01-29T15:15:41', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '75eaaeaa-7146-42ee-a8a3-205f986adf2c'	System	29 Jan 2021 20:15:49
User entered 'No (N)'	System	29 Jan 2021 20:15:49

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-01-29T15:15:44', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '75eaaeaa-7146-42ee-a8a3-205f986adf2c'	System	29 Jan 2021 20:15:49
User entered '29 Jan 2021 15:15:44'	System	29 Jan 2021 20:15:49

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-02-06T18:36:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7db359ff-6813-4393-aad1-0c9cedb5a8bc'	System	06 Feb 2021 23:36:10
User entered 'No (N)'	System	06 Feb 2021 23:36:10



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-02-06T18:36:03', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7db359ff-6813-4393-aad1-0c9cedb5a8bc'	System	06 Feb 2021 23:36:10
User entered 'No (N)'	System	06 Feb 2021 23:36:10

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-02-06T18:36:08', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '7db359ff-6813-4393-aad1-0c9cedb5a8bc'	System	06 Feb 2021 23:36:10
User entered '06 Feb 2021 18:36:08'	System	06 Feb 2021 23:36:10

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-02-14T17:44:18', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6c4ae74e-1e7e-4ad5-a26a-b5f976983395'	System	14 Feb 2021 22:44:28
User entered 'No (N)'	System	14 Feb 2021 22:44:28

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-02-14T17:44:20', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6c4ae74e-1e7e-4ad5-a26a-b5f976983395'	System	14 Feb 2021 22:44:28
User entered 'No (N)'	System	14 Feb 2021 22:44:28

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-02-14T17:44:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '6c4ae74e-1e7e-4ad5-a26a-b5f976983395'	System	14 Feb 2021 22:44:28
User entered '14 Feb 2021 17:44:23'	System	14 Feb 2021 22:44:28



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-02-20T18:19:23', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8c3a8ad5-ae6a-4186-827b-a15e11c566f3'	System	20 Feb 2021 23:19:37
User entered 'No (N)'	System	20 Feb 2021 23:19:37

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-02-20T18:19:26', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8c3a8ad5-ae6a-4186-827b-a15e11c566f3'	System	20 Feb 2021 23:19:37
User entered 'No (N)'	System	20 Feb 2021 23:19:37

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-02-20T18:19:33', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8c3a8ad5-ae6a-4186-827b-a15e11c566f3'	System	20 Feb 2021 23:19:37
User entered '20 Feb 2021 18:19:33'	System	20 Feb 2021 23:19:37

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-02-26T15:20:50-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c7af1e20-586c-4f9c-9a4a-130643a228d2'	System	26 Feb 2021 20:21:01
User entered 'No (N)'	System	26 Feb 2021 20:21:01

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-02-26T15:20:53-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c7af1e20-586c-4f9c-9a4a-130643a228d2'	System	26 Feb 2021 20:21:01
User entered 'No (N)'	System	26 Feb 2021 20:21:01

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-02-26T15:20:55-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'c7af1e20-586c-4f9c-9a4a-130643a228d2'	System	26 Feb 2021 20:21:01
User entered '26 Feb 2021 15:20:55'	System	26 Feb 2021 20:21:01

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-03-07T10:28:19-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '5006ca58-1154-44a6-bdce-22eafd993b7d' User entered 'No (N)'	System	07 Mar 2021 15:28:53
	System	07 Mar 2021 15:28:53



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-03-07T10:28:23-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '5006ca58-1154-44a6-bdce-22eafd993b7d'	System	07 Mar 2021 15:28:53
User entered 'No (N)'	System	07 Mar 2021 15:28:53

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-07T10:28:49-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '5006ca58-1154-44a6-bdce-22eafd993b7d' User entered '07 Mar 2021 10:28:49'	System	07 Mar 2021 15:28:53
	System	07 Mar 2021 15:28:53

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-03-14T17:17:08-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8727f8f7-79e4-413f-a3ea-18097f786946'	System	14 Mar 2021 21:17:20
User entered 'No (N)'	System	14 Mar 2021 21:17:20

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-03-14T17:17:12-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8727f8f7-79e4-413f-a3ea-18097f786946'	System	14 Mar 2021 21:17:20
User entered 'No (N)'	System	14 Mar 2021 21:17:20

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-14T17:17:15-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '8727f8f7-79e4-413f-a3ea-18097f786946'	System	14 Mar 2021 21:17:20
User entered '14 Mar 2021 17:17:15'	System	14 Mar 2021 21:17:20



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-03-22T16:22:43-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2d6ea269-f73b-4164-87b6-b145a66f6c05'	System	22 Mar 2021 20:22:51
User entered 'No (N)'	System	22 Mar 2021 20:22:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-03-22T16:22:45-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2d6ea269-f73b-4164-87b6-b145a66f6c05'	System	22 Mar 2021 20:22:51
User entered 'No (N)'	System	22 Mar 2021 20:22:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-22T16:22:47-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '2d6ea269-f73b-4164-87b6-b145a66f6c05'	System	22 Mar 2021 20:22:51
User entered '22 Mar 2021 16:22:47'	System	22 Mar 2021 20:22:51

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-03-29T03:23:44-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '9743ff03-7b93-4399-ab90-a2c16e5880e7' User entered 'No (N)'	System	29 Mar 2021 07:23:56
	System	29 Mar 2021 07:23:56

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-03-29T03:23:47-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '9743ff03-7b93-4399-ab90-a2c16e5880e7'	System	29 Mar 2021 07:23:56
User entered 'No (N)'	System	29 Mar 2021 07:23:56

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-29T03:23:49-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '9743ff03-7b93-4399-ab90-a2c16e5880e7' User entered '29 Mar 2021 03:23:49'	System	29 Mar 2021 07:23:56
	System	29 Mar 2021 07:23:56

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-04-02T18:33:17-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '908f7b3c-37d9-49d7-9399-69355accf067'	System	02 Apr 2021 22:33:30
User entered 'No (N)'	System	02 Apr 2021 22:33:30



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-04-02T18:33:00-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '908f7b3c-37d9-49d7-9399-69355accf067'	System	02 Apr 2021 22:33:30
User entered 'No (N)'	System	02 Apr 2021 22:33:30

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-04-02T18:33:26-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '908f7b3c-37d9-49d7-9399-69355accf067'	System	02 Apr 2021 22:33:30
User entered '02 Apr 2021 18:33:26'	System	02 Apr 2021 22:33:30

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-04-12T07:07:35-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4f1e9790-fff6-4075-9df3-45bf1d283c3d' User entered 'No (N)'	System	12 Apr 2021 11:07:46

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-04-12T07:07:39-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4f1e9790-fff6-4075-9df3-45bf1d283c3d'	System	12 Apr 2021 11:07:46
User entered 'No (N)'	System	12 Apr 2021 11:07:46

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-04-12T07:07:41-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '4f1e9790-fff6-4075-9df3-45bf1d283c3d' User entered '12 Apr 2021 07:07:41'	System	12 Apr 2021 11:07:46
	System	12 Apr 2021 11:07:46



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-04-18T11:33:13-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a555de32-d938-462e-bcb4-f39d8a065eb4'	System	18 Apr 2021 15:33:23
User entered 'No (N)'	System	18 Apr 2021 15:33:23

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-04-18T11:33:16-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a555de32-d938-462e-bcb4-f39d8a065eb4'	System	18 Apr 2021 15:33:23
User entered 'No (N)'	System	18 Apr 2021 15:33:23

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-04-18T11:33:19-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'a555de32-d938-462e-bcb4-f39d8a065eb4'	System	18 Apr 2021 15:33:23
User entered '18 Apr 2021 11:33:19'	System	18 Apr 2021 15:33:23

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-04-26T12:21:33-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '165e8828-7ff2-4c87-8244-bbdfaf110b9'	System	26 Apr 2021 16:21:47
User entered 'No (N)'	System	26 Apr 2021 16:21:47

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-04-26T12:21:37-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '165e8828-7ff2-4c87-8244-bbdfaf110b9' User entered 'No (N)'	System	26 Apr 2021 16:21:47

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-04-26T12:21:39-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '165e8828-7ff2-4c87-8244-bbdfaf110b9'	System	26 Apr 2021 16:21:47
User entered '26 Apr 2021 12:21:39'	System	26 Apr 2021 16:21:47

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[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 (8febb5081b9c711f)', Time: '2021-05-03T12:01:37-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '01e3d6af-348a-4174-aa85-2cd028d2829e'	System	03 May 2021 16:06:31
User entered 'No (N)'	System	03 May 2021 16:06:31



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

Have you been exposed to someone with 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 (8febb5081b9c711f)', Time: '2021-05-03T12:01:39-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '01e3d6af-348a-4174-aa85-2cd028d2829e'	System	03 May 2021 16:06:31
User entered 'No (N)'	System	03 May 2021 16:06:31

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-05-03T12:01:42-04:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: '01e3d6af-348a-4174-aa85-2cd028d2829e'	System	03 May 2021 16:06:31
User entered '03 May 2021 12:01:42'	System	03 May 2021 16:06:31

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:09:32



**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:09:32

**US3742022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:32
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:09:32

US3742022

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:28:13**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:33:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-04T12:35:48-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'd951234e-0932-4b6d-92ed-f26491807991'	System	04 Mar 2021 17:35:59
User entered 'No (N)'	System	04 Mar 2021 17:35:59

**US3742022**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:33:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8febb5081b9c711f)', Time: '2021-03-04T12:35:51-05:00', User OID: 'PatientReportedOutcome (US3742022)', ODM File OID: 'd951234e-0932-4b6d-92ed-f26491807991'	System	04 Mar 2021 17:35:59
User entered '04 Mar 2021 12:35:51'	System	04 Mar 2021 17:35:59

**US3742022**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	11 Nov 2020 20:14:46

**US3742022**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '11 Nov 2020'	Sherry McCammon (b) (4)	11 Nov 2020 20:14:46

US3742022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	11 Nov 2020 20:14:46



US3742022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Sherry McCammon (b) (4)	11 Nov 2020 20:14:46

US3742022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	11 Nov 2020 20:14:53

**US3742022**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:41:19
User entered 'I'	System	11 Nov 2020 20:14:53

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 12:44:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 12:44:40
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	22 Jan 2021 12:44:40
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:10:31
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).	System	21 Jan 2021 21:10:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:10:31
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:07:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 21:07:44
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	21 Jan 2021 21:07:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:07:44
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:04:52
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).	System	21 Jan 2021 21:04:52

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:04:52
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	21 Jan 2021 21:02:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:02:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Jan 2021 21:00:45

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	27 Jan 2021 07:30:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:10:31
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:07:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:04:52
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with '14jan2021' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 21:03:43
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	21 Jan 2021 21:03:02
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:03:02
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:00:45

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:00:45

US3742022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:00:45



US3742022

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 12:44:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 12:44:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	22 Jan 2021 12:44:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:10:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:08:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 21:08:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:08:34
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:08:28
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:08:28

US3742022

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User entered 'I'	System	22 Jan 2021 12:44:55
User entered empty.	System	21 Jan 2021 21:10:44
User entered 'I'	System	21 Jan 2021 21:08:34
User entered empty.	System	21 Jan 2021 21:08:28

US3742022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 21:09:52

US3742022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 21:09:52

US3742022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 21:09:52

US3742022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:09:52

US3742022

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:10:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 21:10:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:10:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:09:59
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 21:09:59

US3742022

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User entered 'I'	System	21 Jan 2021 21:10:03
User entered empty.	System	21 Jan 2021 21:09:59



US3742022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 14:49:57
	(b) (4)	

US3742022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '12 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 14:49:57
	(b) (4)	

US3742022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	15 Feb 2021 14:49:57
	(b) (4)	

US3742022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	15 Feb 2021 14:49:57
	(b) (4)	

US3742022

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 14:50:04
	(b) (4)	

US3742022

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:24
User entered 'I'	System	15 Feb 2021 14:50:04

**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:16

US3742022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '17 Mar 2021'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:16



US3742022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:16

**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered 'VISIT4'	System	17 Mar 2021 15:17:16

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered empty.	System	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49



**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered empty.	System	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered empty.	System	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered empty.	System	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	30 Mar 2021 18:56:49



US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered empty.	System	30 Mar 2021 18:56:49

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47

US3742022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47

US3742022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:41

US3742022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:17:41

US3742022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:17:34

US3742022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '17 Mar 2021'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:34

**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '09:55'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:34



**US3742022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered '17 Mar 2021 09:55'	System	17 Mar 2021 15:17:34

US3742022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Mar 2021 15:17:46

US3742022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:47
User entered 'I'	System	17 Mar 2021 15:17:46

**US3742022**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:19:41
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Apr 2021 13:59:22
	(b) (4)	

US3742022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:19:41
	(b) (4)	
User entered '15 Apr 2021'	Sherry McCammon (b) (4)	19 Apr 2021 13:59:22
	(b) (4)	

**US3742022**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:19:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	19 Apr 2021 13:59:22

US3742022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:19:41
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	19 Apr 2021 13:59:22
	(b) (4)	

**US3742022**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:19:41
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Apr 2021 13:59:28
	(b) (4)	



**US3742022**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:59:28

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:13

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:51:17
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:24:30

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:13

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:51:17
User entered '14:20'	(b) (4), (b) (6)	03 Dec 2020 17:24:30

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:13

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:21
User entered '02 Dec 2020 14:20'	System	03 Dec 2020 17:24:30

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:13

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:51:17
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	03 Dec 2020 17:24:30

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:13

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:24:30

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:45:53
Query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:14:28
User opened query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:10:19
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 1 (Day 1)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '24 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	Hassan Haji (b) (4)	08 Dec 2020 15:55:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
User closed query 'Per CDM: It appears that O2 and Temperature were not collected. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:42:24
Query 'Per CDM: It appears that O2 and Temperature were not collected. If not collected, please consider recording as Not Done.' answered with 'ND- NOT DONE ENTERED' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 14:15:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User opened query 'Per CDM: It appears that O2 and Temperature were not collected. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:30:39
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:55:56

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:45:56
Query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:15:17
User opened query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:26:00
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 2 (Day 2)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '25 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	Hassan Haji (b) (4)	08 Dec 2020 15:57:31
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:57:31

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:38
Query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in the source' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:16:34
User opened query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:51:10
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 3 (Day 3)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '26 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	Hassan Haji (b) (4)	08 Dec 2020 15:58:59
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 15:58:59



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:41
Query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in the source' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:17:50
User opened query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:51:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 4 (Day 4)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '27 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:31:11
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	Hassan Haji (b) (4)	08 Dec 2020 16:01:13
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:01:13

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:45
Query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:18:37
User opened query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:09:20
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 5 (Day 5)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '28 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:18:55
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:18:55
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:18:55
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 16:02:58
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:02:58

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:48
Query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:19:35
User opened query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:09:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 6 (Day 6)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '29 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:19:51
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:19:51
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 16:19:51
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	Hassan Haji (b) (4)	08 Dec 2020 16:05:09
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:05:09

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:53
Query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source doc' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:28:24
User opened query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:09:52
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 7 (Day 7)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '30 Nov 2020'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:28:39
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:28:39
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:28:39
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered '1'	(b) (4)	
	Hassan Haji (b) (4)	08 Dec 2020 16:06:27
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'Mild (Mild)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:53:21
User entered 'None (None)'	Hassan Haji (b) (4) (b) (4)	08 Dec 2020 16:06:27



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User closed query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:46:58
Query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'confirmed symptoms are in source doc' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 16:29:50
User opened query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 02 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 05:25:40
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 8 (Day 8)'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '01 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:42:34
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:56:43
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:30:06
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:30:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 16:30:06
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	23 Jan 2021 14:14:46
User entered empty.	System	15 Dec 2020 17:20:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:51:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Jan 2021 14:14:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Jan 2021 14:14:46
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 9 (Day 9)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Dec 2020 17:21:14
User entered '02 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:21:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Dec 2020 17:20:56
User entered '0 Dec 2020' (non-conformant).	Sherry McCammon (b) (4)	15 Dec 2020 17:20:56



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:56

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:42
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:56

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:07:42
User entered empty.	System	15 Dec 2020 17:20:56

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:42
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:20:56

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:20:56
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 10 (Day 10)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '03 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:24

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:24

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:42
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:24



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:07:42
User entered empty.	System	15 Dec 2020 17:21:24

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:42
User entered '96.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:07:42
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:24

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:24
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 11 (Day 11)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '04 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:38

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:38

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	15 Dec 2020 17:21:38

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '96.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:38



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	



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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:08
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	

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Form: Symptom Log (11)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:38
	(b) (4)	



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 12 (Day 12)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '05 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:51

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:51

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Form: Symptom Log (12)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:51

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Form: Symptom Log (12)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	15 Dec 2020 17:21:51

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Form: Symptom Log (12)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:21:51

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	



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Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

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Form: Symptom Log (12)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:21:51
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 13 (Day 13)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '06 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:05



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:05

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:05

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	15 Dec 2020 17:22:05

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:05

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 14 (Day 14)'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '07 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:16

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:16

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:16



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	15 Dec 2020 17:22:16

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:22:16

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:25:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:23:41
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:30:27
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:31:47
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:32:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	



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Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:33:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:34:49
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:35:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:36:39
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:37:21
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:07
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:30
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:38:48
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:22:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:06:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:06:38
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:55:50
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '97.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:06:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:06:38
User entered '09 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:55:50
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:28:13**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:06:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:06:38
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:55:50
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:55:50

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:06:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:06:38
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:55:50
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

**US3742022**

**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 10 Jun 2021 09:28:13**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:06:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:06:38
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 18:55:50
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

**US3742022**

**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 10 Jun 2021 09:28:13**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38
User entered empty.	System	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

**US3742022**

**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 10 Jun 2021 09:28:13**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:06:38
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 18:55:50



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:06:38

**US3742022**

**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 10 Jun 2021 09:28:13**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '13 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '97.6' F	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:06:38

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:09:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 19:09:52
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 19:08:03
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:09:52
User entered empty.	System	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:09:52
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 19:08:03

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Day 22 (Day 22)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '15 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98'	(b) (4), (b) (6)	29 Dec 2020 19:09:52



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User entered '%'	System	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered '98.5' F	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 09:28:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:51:55
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 19:09:52

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:32
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[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 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[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 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 11:46:49
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 17:04:15
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive ' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 17:02:16
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	09 Dec 2020 16:59:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 16:59:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 10:25:16
Query 'Data is required. Please complete.' answered with 'will update when result is available ' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	03 Dec 2020 20:24:14
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:26:22
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:26:22

**US3742022**

**Folder: Covid-19 Assessment 02 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:13**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:38
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:42
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:26:22



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[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 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:44
User entered 'No (N)'	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:46
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:48
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:26:22

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:13

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:36
User entered 'I'	System	09 Dec 2020 16:59:45

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Generated On: 10 Jun 2021 09:28:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Generated On: 10 Jun 2021 09:28:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Folder: Covid-19 Assessment 02 Dec 2020

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Generated On: 10 Jun 2021 09:28:13

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:19:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' answered with 'corrected' (Site from DM).	Sherry McCammon (b) (4)	15 Feb 2021 16:59:57
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:21:05
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4)	09 Dec 2020 21:13:36

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Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:43:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:59:48
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:59:48
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Folder: Covid-19 Assessment 02 Dec 2020

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Please review Evidence of Shock as it appears several responses are missing and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:56:31
Query 'Per CDM: Please review Evidence of Shock as it appears several responses are missing and update accordingly.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 14:09:52
User opened query 'Per CDM: Please review Evidence of Shock as it appears several responses are missing and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:49:46
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Evidence of Shock Requires  
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:53:06
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:53:06
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:53:06
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:53:06
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36



US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:53:06
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 14:09:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:28:13

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:23:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	09 Dec 2020 21:13:36

US3742022

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:28:13

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:13:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:15:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:24:33



**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 3 (Day 3)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered '04 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 5 (Day 5)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered '06 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 7 (Day 7)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53



**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered '08 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered '10 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 14 (Day 14)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:09:06
User closed query 'Please change to yes since sample was collected and processed.' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 16:08:58
Query 'Please change to yes since sample was collected and processed.' answered with 'changed' (Site from CRA).	Sherry McCammon (b) (4)	12 Jan 2021 20:43:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:43:29
User opened query 'Please change to yes since sample was collected and processed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:48:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 15:57:48
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'No (N)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:28:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:09:06
User entered '15 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:43:19
DataPoint Un-verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	06 Jan 2021 15:57:48
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered empty.	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 21 (Day 21)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	



US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:28:13

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Please change to yes since sample was collected and processed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:09:32
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:09:06
Query 'Please change to yes since sample was collected and processed.' answered with 'changed' (Site from CRA).	Sherry McCammon (b) (4)	12 Jan 2021 20:43:55
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 20:43:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:43:29
User opened query 'Please change to yes since sample was collected and processed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:22
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'No (N)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:28:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:09:06
DataPoint Un-verified.	Sherry McCammon (b) (4)	12 Jan 2021 20:43:19
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	12 Jan 2021 20:43:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered empty.	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

**US3742022**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User accepted default value 'Day 28 (Day 28)'	Sherry McCammon (b) (4)	11 Dec 2020 15:55:53
	(b) (4)	

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:28:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 16:49:53
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:49:53
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

US3742022

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:28:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:37:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 16:49:53
User entered '29 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:49:53
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 21:51:03
User entered empty.	Sherry McCammon (b) (4) (b) (4)	11 Dec 2020 15:55:53

US3742022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:45:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 06:29:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 14:17:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:34:43
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:26:58

US3742022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:45:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 06:29:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 14:17:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:36:29
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 04DEC2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 04:48:36
Query 'Per GCL Lab Recon: Saliva: Sample dated 04DEC2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, Thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 19:36:55
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 04DEC2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:45:23
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:01

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EAB) (1725)

2390 of 3292

US3742022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:26:58



US3742022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[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 07:45:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Dec 2020 17:26:58

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:45:56
User entered 'SICKD1'	System	03 Dec 2020 17:26:58

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '14:20'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User entered '02 Dec 2020 14:20'	System	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '64.0' in	(b) (4), (b) (6)	03 Dec 2020 17:27:47
DataPoint set to visible.	System	03 Dec 2020 17:26:58

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '241.1' lb	(b) (4), (b) (6)	03 Dec 2020 17:27:47
DataPoint set to visible.	System	03 Dec 2020 17:26:58



US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '098.4' F	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '076'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User entered 'bpm'	System	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '24'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User entered 'breaths/min'	System	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '140'	(b) (4), (b) (6)	03 Dec 2020 17:27:47



US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User entered 'mmHg'	System	03 Dec 2020 17:27:47

**US3742022**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:57:37
User entered '090'	(b) (4), (b) (6)	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07
User entered 'mmHg'	System	03 Dec 2020 17:27:47

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07

US3742022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:07

US3742022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:27:56

US3742022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:48
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:27:56

US3742022

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:28:13

[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 07:46:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:28:05



**US3742022**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 10 Jun 2021 09:28:13**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:57
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:28:05

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:53:57
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:47:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 08:11:09
Query 'Data is required. Please complete.' answered with 'ENTERED IN ERROR' (Site from System).	Sherry McCammon (b) (4)	15 Dec 2020 17:15:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	15 Dec 2020 17:15:43
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:15:43
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Dec 2020 17:13:20
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:53:57
User entered '29 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:47:57
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:15:43
User entered '02 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:13:20
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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 07:46:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:53:57
User entered 'Clinic (Clinic)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:47:57
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:15:43
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	15 Dec 2020 17:13:32
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:13:32
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	15 Dec 2020 17:13:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	15 Dec 2020 17:13:20

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:46:59
User entered 'SICKD28'	System	30 Dec 2020 16:47:57
User entered empty.	System	15 Dec 2020 17:15:43
User entered 'SICKD28'	System	15 Dec 2020 17:13:20

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'ENTERED IN ERROR' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 08:11:15
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	15 Dec 2020 17:16:47
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	15 Dec 2020 17:16:39
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '29 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '02 Dec 2020'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '15:11' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '14:20'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	



US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User entered '29 Dec 2020 15:11'	System	12 Jan 2021 20:36:30
User entered empty.	System	15 Dec 2020 17:16:39
User entered '02 Dec 2020 14:20'	System	15 Dec 2020 17:14:33

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Please verify height should be 65in per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:08:19
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:07:54
User closed query 'Per CDM: please confirm if vital signs are required and remove data if not, or otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:48:18
Query 'Per CDM: please confirm if vital signs are required and remove data if not, or otherwise clarify.' answered with 'REQUIRED' (Site from DM).	Sherry McCammon (b) (4)	12 Jan 2021 20:37:25
Query 'Please verify height should be 65in per source.' answered with 'VERIFIED' (Site from CRA).	(b) (4)	12 Jan 2021 20:37:06
User entered '65.0' in reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User opened query 'Per CDM: please confirm if vital signs are required and remove data if not, or otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:55:17
User opened query 'Please verify height should be 65in per source.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:50:39
DataPoint set to visible.	System	30 Dec 2020 16:47:57
DataPoint set to invisible.	System	15 Dec 2020 17:15:43
User entered '64' in	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
DataPoint set to visible.	(b) (4) System	15 Dec 2020 17:13:20

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Please verify weight should be 245.1 per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 16:07:54
Query 'Please verify weight should be 245.1 per source.' answered with 'VERIFIED' (Site from CRA).	Sherry McCammon (b) (4)	12 Jan 2021 20:37:37
User entered '245.1' lb reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:36:30
User opened query 'Please verify weight should be 245.1 per source.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:51:01
DataPoint set to visible.	System	30 Dec 2020 16:47:57
DataPoint set to invisible.	System	15 Dec 2020 17:15:43
User entered '241.1' lb	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
DataPoint set to visible.	(b) (4) System	15 Dec 2020 17:13:20

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '098.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '098.4' F	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered 'Other (Other)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered 'NOT SPECIFIED- NEED INFO' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '066' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '076'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User entered 'bpm'	System	12 Jan 2021 20:36:30
User entered empty.	System	15 Dec 2020 17:16:39
User entered 'bpm'	System	15 Dec 2020 17:14:33



US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '13' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '24'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User entered 'breaths/min'	System	12 Jan 2021 20:36:30
User entered empty.	System	15 Dec 2020 17:16:39
User entered 'breaths/min'	System	15 Dec 2020 17:14:33

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '139' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '140'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User entered 'mmHg'	System	12 Jan 2021 20:36:30
User entered empty.	System	15 Dec 2020 17:16:39
User entered 'mmHg'	System	15 Dec 2020 17:14:33

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:07:54
User entered '082' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Jan 2021 20:36:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:16:39
	(b) (4)	
User entered '090'	Sherry McCammon (b) (4)	15 Dec 2020 17:14:33
	(b) (4)	

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12
User entered 'mmHg'	System	12 Jan 2021 20:36:30
User entered empty.	System	15 Dec 2020 17:16:39
User entered 'mmHg'	System	15 Dec 2020 17:14:33

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:12



US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 16:49:04

US3742022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:45
User entered '29 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 16:49:04

US3742022

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:28:13

[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 07:47:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 16:49:24

US3742022

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:28:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:47:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:53
User entered '29 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 16:49:24

**US3742022**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:11

US3742022

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

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:11

US3742022

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

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:11

**US3742022**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 20:48:11



US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:29
Signature has been broken.	Sherry McCammon (b) (4)	12 Apr 2021 15:57:17
User entered '20 Jan 2021' reason for change: Data Entry Error	Sherry McCammon (b) (4)	12 Apr 2021 15:57:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '6 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 20:49:07

**US3742022**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:13**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:29
User entered '0'	Sherry McCammon (b) (4)	12 Apr 2021 15:57:17
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:06:10

US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07

**US3742022**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:13**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:34:29
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Sherry McCammon (b) (4)	12 Apr 2021 15:57:17
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 17:06:10

US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07

US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07

US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07

US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07



US3742022

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

Form: Unblinding

Generated On: 10 Jun 2021 09:28:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:07

**US3742022**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:13**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '1'	System	21 Jan 2021 20:49:07

**US3742022**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'I'	System	21 Jan 2021 20:49:07

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	21 Jan 2021 20:57:06
DataPoint set to visible.	System	21 Jan 2021 20:49:07

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06



US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	21 Jan 2021 20:57:06
DataPoint set to visible.	System	21 Jan 2021 20:49:07

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '07:42'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '20 Jan 2021 07:42'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06



US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '062'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'bpm'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'breaths/min'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '145'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '098'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06



US3742022

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	21 Jan 2021 20:57:06
DataPoint set to visible.	System	21 Jan 2021 20:49:07

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '08:42'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06



**US3742022**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '20 Jan 2021 08:42'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '057'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'bpm'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '13'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'breaths/min'	System	21 Jan 2021 20:57:06



US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '156'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

**US3742022**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '096'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:57:06

US3742022

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mmHg'	System	21 Jan 2021 20:57:06

US3742022

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:51:54

US3742022

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:51:54

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44



US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	21 Jan 2021 20:49:44
	(b) (4), (b) (6)	

US3742022

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:44

**US3742022**

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

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered empty.	System	21 Jan 2021 20:49:44

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26



US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'mRNA-1273'	System	21 Jan 2021 20:52:26
DataPoint set to visible.	System	21 Jan 2021 20:49:07

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '08:07'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26

**US3742022**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '20 Jan 2021 08:07'	System	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'ONCE'	System	21 Jan 2021 20:52:26

US3742022

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

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 20:52:26



US3742022

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:30

US3742022

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:30

**US3742022**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '07:32'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:30

**US3742022**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '20 Jan 2021 07:32'	System	21 Jan 2021 20:48:30

US3742022

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:46

US3742022

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:46

**US3742022**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '07:36'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:48:46

**US3742022**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:13**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered '20 Jan 2021 07:36'	System	21 Jan 2021 20:48:46



US3742022

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

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:49:25

**US3742022**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:25:58
User entered 'I'	System	21 Jan 2021 20:49:25

**US3742022**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4)	29 Jan 2021 16:47:40
	(b) (4), (b) (6)	

US3742022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '27 Jan 2021'	(b) (4)	29 Jan 2021 16:47:40
	(b) (4), (b) (6)	

US3742022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:40

US3742022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	29 Jan 2021 16:47:40
	(b) (4), (b) (6)	

US3742022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:56

**US3742022**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User entered 'I'	System	29 Jan 2021 16:47:56



**US3742022**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:00
User entered 'I'	System	29 Jan 2021 16:47:56
DataPoint set to visible.	System	29 Jan 2021 16:47:56

**US3742022**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:58:35

**US3742022**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4)	17 Feb 2021 21:58:35
	(b) (4), (b) (6)	

US3742022

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:13

[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 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:58:35

**US3742022**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'OLD29'	System	17 Feb 2021 21:58:35

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01



US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '08:00'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered '17 Feb 2021 08:00'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Oral (Oral)'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '078'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'bpm'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01



**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'breaths/min'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '154'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'mmHg'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '085'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'mmHg'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01



US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '08:37'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered '17 Feb 2021 08:37'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Other (Other)'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '071'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'bpm'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '16'	(b) (4)	17 Feb 2021 22:07:01
	(b) (4), (b) (6)	



US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'breaths/min'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '140'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'mmHg'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '082'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 22:07:01

**US3742022**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'mmHg'	System	17 Feb 2021 22:07:01

US3742022

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4)	17 Feb 2021 21:59:26
	(b) (4), (b) (6)	

US3742022

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:26

US3742022

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:58:59



US3742022

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4)	17 Feb 2021 21:58:59
	(b) (4), (b) (6)	

US3742022

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:58:59

US3742022

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:28:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:58:59

**US3742022**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4)	17 Feb 2021 21:58:59
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	17 Feb 2021 21:58:59
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	17 Feb 2021 21:58:59
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered empty.	System	17 Feb 2021 21:58:59

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:46



US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4)	17 Feb 2021 21:59:46
	(b) (4), (b) (6)	

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

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 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:46

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'mRNA-1273'	System	17 Feb 2021 21:59:46
DataPoint set to visible.	System	29 Jan 2021 16:47:56

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:46

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '08:06'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:46

**US3742022**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered '17 Feb 2021 08:06'	System	17 Feb 2021 21:59:46

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:59:46

US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'ONCE'	System	17 Feb 2021 21:59:46



US3742022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 21:59:46

US3742022

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4)	17 Feb 2021 21:58:42
	(b) (4), (b) (6)	

**US3742022**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:02:03
User entered 'I'	System	17 Feb 2021 21:58:42

**US3742022**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Feb 2021 15:56:01

**US3742022**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '24 Feb 2021'	Sherry McCammon (b) (4)	25 Feb 2021 15:56:01

US3742022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Feb 2021 15:56:01

**US3742022**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	25 Feb 2021 15:56:01

**US3742022**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Feb 2021 15:56:12



**US3742022**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:32:59
User entered 'I'	System	25 Feb 2021 15:56:12

**US3742022**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:18:39

**US3742022**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '17 Mar 2021'	Sherry McCammon (b) (4)	17 Mar 2021 15:18:39

**US3742022**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[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 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	17 Mar 2021 15:18:39

**US3742022**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered 'OLD57'	System	17 Mar 2021 15:18:39

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00



**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered empty.	System	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered empty.	System	17 Mar 2021 15:19:00

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered empty.	System	17 Mar 2021 15:19:00



US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered empty.	System	17 Mar 2021 15:19:00

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:00

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered empty.	System	17 Mar 2021 15:19:00

US3742022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49

**US3742022**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49

US3742022

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Mar 2021 15:19:06

US3742022

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 15:19:06



US3742022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:18:53

US3742022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '17 Mar 2021'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:18:53

**US3742022**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
User entered '09:55'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 15:18:53

**US3742022**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:49
User entered '17 Mar 2021 09:55'	System	17 Mar 2021 15:18:53

US3742022

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:28:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:23
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Hassan Haji (b) (4)	12 Sep 2020 20:08:39

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:18:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:18:47
Data point term sent to Coder	System	12 Sep 2020 20:17:30
User entered 'lower back pain'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:14:31
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 18:08:01
User entered '24 Aug 2020'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Per CDM: Please note Start Time is not required, unless start time of AE is within 24 hours of dosing time, then the field must be completed. Please consider to remove start time. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 10:14:59
Query 'Per CDM: Please note Start Time is not required, unless start time of AE is within 24 hours of dosing time, then the field must be completed. Please consider to remove start time. ' answered with 'START TIME REMOVED ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 18:53:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:53:26
User opened query 'Per CDM: Please note Start Time is not required, unless start time of AE is within 24 hours of dosing time, then the field must be completed. Please consider to remove start time. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:49:50
Query 'Per CDM: Please note Start Time is not required, unless start time of AE is within 24 hours of dosing time, then the field must be completed ' canceled (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:49:31
User opened query 'Per CDM: Please note Start Time is not required, unless start time of AE is within 24 hours of dosing time, then the field must be completed ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:44:24
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 11:43:43
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'correct time entered ' (Site from System).	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:17:00
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Sep 2020 20:16:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:00'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User entered empty.	System	16 Sep 2020 18:53:26
User entered '24 Aug 2020 11:00'	System	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '24 Aug 2020'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37



US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Per CDM: Please note End Time is not required, unless end time of AE is within 24 hours after dosing time, then the field must be completed. Kindly consider removing End Time. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 10:17:57
Query 'Per CDM: Please note End Time is not required, unless end time of AE is within 24 hours after dosing time, then the field must be completed. Kindly consider removing End Time. ' answered with 'STOP TIME REMOVED' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 18:54:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:54:32
User opened query 'Per CDM: Please note End Time is not required, unless end time of AE is within 24 hours after dosing time, then the field must be completed. Kindly consider removing End Time. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:44:34
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 11:43:45
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'correct time entered ' (Site from System).	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:17:12
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Sep 2020 20:16:37
User entered '20:30'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User entered empty.	System	16 Sep 2020 18:54:32
User entered '24 Aug 2020 20:30'	System	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

US3742022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:18:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 20:18:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:18:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:16:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:18:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 20:18:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:18:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:16:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:18:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 20:18:56
User entered 'None (NONE)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:18:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:16:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Sep 2020 20:18:56
User entered '1' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:18:56
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Sep 2020 20:16:37
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:19:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 20:19:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:19:21
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 20:16:37
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:13

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 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User entered '0'	System	12 Sep 2020 20:16:37



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10
User entered '0'	System	12 Sep 2020 20:16:37

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
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: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:24
Data point term sent to Coder	System	07 Oct 2020 19:39:07
User entered 'injection site pain'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '3 Oct 2020'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 14:44:30
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'right time entered' (Site from System).	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:43
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 19:38:15
User entered '13:00'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User entered '3 Oct 2020 13:00'	System	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User entered empty.	System	07 Oct 2020 19:38:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15



US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'l'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

US3742022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15



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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:28:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[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 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User entered '0'	System	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05
User entered '0'	System	07 Oct 2020 19:38:15

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:05

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:38
Data point term sent to Coder	System	07 Oct 2020 19:42:17
User entered 'loose stool'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '4 Oct 2020'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User entered empty.	System	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '4 Oct 2020'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User entered empty.	System	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'l'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[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 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:41:20

US3742022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User entered '0'	System	07 Oct 2020 19:41:20



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02
User entered '0'	System	07 Oct 2020 19:41:20

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:33:02

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:59:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:59:08
Data point term sent to Coder	System	23 Nov 2020 19:58:31
User entered 'sinus infection'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Please verify this should be yes since subject saw physician and was prescribed medication' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:26
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
Query 'Please verify this should be yes since subject saw physician and was prescribed medication' answered with 'updated' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 17:22:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Dec 2020 17:22:48
User opened query 'Please verify this should be yes since subject saw physician and was prescribed medication' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:03:40
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '18 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User entered empty.	System	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4)	
Query 'Per MM, please provide the end date.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 19:32:39
DataPoint Un-verified.	Sherry McCammon (b) (4)	15 Dec 2020 17:12:20
	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
	(b) (4)	
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 21:11:38
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User entered empty.	System	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

US3742022

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	15 Dec 2020 17:12:30
DataPoint Un-verified.	Sherry McCammon (b) (4)	15 Dec 2020 17:12:30
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:12:30
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	
DataPoint Verified.	System	15 Dec 2020 17:11:45
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '1'	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Un-verified.	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:11:45
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:11:45
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4)	23 Nov 2020 19:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Dec 2020 17:11:23
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:06:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:06:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:06:56
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:58:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[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 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:58:10

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User entered '0'	System	25 Nov 2020 17:06:56

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59
User entered '1'	System	09 Dec 2020 17:22:48
User entered '0'	System	25 Nov 2020 17:06:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:01:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:01:07
Data point term sent to Coder	System	23 Nov 2020 20:00:33
User entered 'loose stool'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:08:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 19:59:39
	Sherry McCammon (b) (4)	23 Nov 2020 19:59:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

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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 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '18 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User entered empty.	System	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:08:03
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	23 Nov 2020 19:59:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '18 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 17:08:03
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Nov 2020 19:59:39
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User entered empty.	System	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:08:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:59:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:08:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:59:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:08:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:59:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39



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Generated On: 10 Jun 2021 09:28:13

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:08:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:59:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'l'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

US3742022

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

US3742022

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:08:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:08:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sherry McCammon (b) (4)	25 Nov 2020 17:08:03
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:59:39
User entered empty.	Sherry McCammon (b) (4)	23 Nov 2020 19:59:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

[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 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Nov 2020 19:59:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User entered '0'	System	25 Nov 2020 17:08:03



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58
User entered '0'	System	25 Nov 2020 17:08:03

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:32:58

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:27:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:34
User entered	System	10 Dec 2020 14:43:23
'USA-US127-2020-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	10 Dec 2020 14:43:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:21:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:21:59
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 17:21:26
Coding entries removed.	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User entered 'covid 19' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 17:25:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 17:25:09
	(b) (4)	
Data point term sent to Coder	System	03 Dec 2020 17:23:53
User entered 'Fatigue'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:23:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:23:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '24 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 17:23:03



**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:46:30
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:46:30
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:16:20
Query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' answered with 'Recovered as of 15DEC2020' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 16:46:30
User entered '15 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:46:30
User opened query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 17:35:26
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Dec 2020 17:23:03

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Dec 2020 17:21:50
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:23:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Form: Adverse Events (6)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:50
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Dec 2020 17:23:03
	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:23:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Generated On: 10 Jun 2021 09:28:13

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 17:21:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:21:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:23:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Dec 2020 17:21:03
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:03
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Dec 2020 17:23:03
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:16:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'No concomitant medications given for diagnoses of SARS-CoV-2 infection' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:43:08
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:43:51
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 17:23:03



US3742022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:47:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:16:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Recovered as of 15DEC2020' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:46:43
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 16:46:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 16:46:30
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 17:35:11
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	03 Dec 2020 17:23:03

US3742022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:50:09
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

US3742022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 18:50:09
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Dec 2020 17:21:50
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Dec 2020 17:21:50
User entered 'Participant is COVID-19 positive' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 17:21:50
	(b) (4)	
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Dec 2020 17:21:03
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:23:03

US3742022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 17:21:03

**US3742022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 17:21:03

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:28:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:23
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 17:48:20
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 17:55:16

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: ELURYNG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 09:03:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:03:55
Data point term sent to Coder	System	16 Sep 2020 18:51:09
User closed query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	System	16 Sep 2020 18:50:54
Query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' answered with 'SPELLING IS CORRECT. GENERIC VERSION OF NUVA RING' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 18:50:54
Data point term sent to Coder	System	16 Sep 2020 18:50:08
User entered 'EluRyng' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:49:57
User opened query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	Coder Import (b) (4) (b) (4)	10 Sep 2020 08:57:35
Data point term sent to Coder	System	08 Sep 2020 18:00:44
User entered 'Elurnyna'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:00:23

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Contraception'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'ring'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'every three weeks'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Vaginal (VAGINAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2018'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:00:23
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:00:23

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:00:23

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:00:23



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 18:10:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:10:54
Data point term sent to Coder	System	08 Sep 2020 18:07:55
User entered 'Fluticasone'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:07:43

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'nasal allergies'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '2'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'sprays'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Nasal (NASAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2015'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:07:43
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:07:43



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:07:43

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:07:43

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 23:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 23:50:58
Data point term sent to Coder	System	08 Sep 2020 18:10:58
User entered 'adderrall XR Generic'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:10:10

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Attention defecit disorder'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '10'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2015'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:10:10
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:10:10

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:10:10

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:10:10

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 18:13:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:13:48
Data point term sent to Coder	System	08 Sep 2020 18:13:03
User entered 'citalopram'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:12:06

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'depression'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '40'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2018'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:12:06
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:12:06

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:12:06

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:12:06

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 06:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:39:43
Data point term sent to Coder	System	08 Sep 2020 18:15:08
User entered 'montelukast'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:14:21

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'seasonal allergies/ asthma'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '10'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2015'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:14:21
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:14:21

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:14:21

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:14:21



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 06:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:29:39
Data point term sent to Coder	System	08 Sep 2020 18:24:32
User entered 'levosalbutamol'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:23:33

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'asthma'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '45'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'ug (ug)'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ASTHMA-UN UNK 2015. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:49:14
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ASTHMA-UN UNK 2015. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED INFORMATION' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 15:13:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of ASTHMA-UN UNK 2015. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:07:20
User entered 'UN UNK 2010'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:23:33

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:23:33
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:23:33



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:23:33

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:23:33

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
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: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 00:03:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 00:03:59
Data point term sent to Coder	System	08 Sep 2020 18:26:43
User entered 'claritin (generic)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'seasonal allergies'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '10'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:26:29
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:26:29

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:26:29

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:26:29

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINONIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 00:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:50:58
Data point term sent to Coder	System	08 Sep 2020 18:33:01
User entered 'FLUOCINONIDE 0.05% solution' reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:32:09
Data point term sent to Coder	System	08 Sep 2020 18:29:52
User entered 'Fluocinonide 0.05%'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:29:48

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Query 'Per DM CLR: Please update the indication to reflect the location and type of ECZEMA,( e.g base of neck, forearm, right leg etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:52:52
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ECZEMA,( e.g base of neck, forearm, right leg etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:07:48
User entered 'eczema'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:29:48

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'more than one'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'drops'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Topical (TOPICAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	



**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:29:48
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:29:48

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:29:48

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:29:48

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINONIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 00:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:50:58
Data point term sent to Coder	System	08 Sep 2020 18:36:09
User entered 'fluocinonide 0.05 %ointment'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:35:45

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Query 'Per DM CLR: Please update the indication to reflect the location and type of ECZEMA,( e.g base of neck, forearm, right leg etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 11:53:02
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ECZEMA,( e.g base of neck, forearm, right leg etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:08:19
User entered 'Eczema'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:35:45

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Dab'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Topical (TOPICAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:35:45
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:35:45

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:35:45

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:35:45



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 00:40:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:40:00
Data point term sent to Coder	System	08 Sep 2020 18:38:12
User entered 'Diazepam'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:37:12

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Generalized anxiety disorder'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '2'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:18:52
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'MEDICAL HISTORY ENTRY #6 GENERALIZED ANXIETY DISORDER REMAINS ONGOING. MEDICATION IS FOR MEDICAL HISTORY ENTRY #6 ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:14:24
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:05:08
User entered 'UN UNK 2010'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:37:12

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:37:12
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:37:12



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:37:12

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:37:12

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 18:40:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:40:53
Data point term sent to Coder	System	08 Sep 2020 18:40:16
User entered 'women's multivitamin'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:39:39

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:28:24
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:00:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:00:09
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:40:42
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:39:39

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'supplement'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'tablet (TABLET)'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:39:39
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:39:39

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:39:39

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:39:39

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 18:42:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:42:48
Data point term sent to Coder User entered 'Vitamin D3'	System Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:41:20 08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:28:36
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:04:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:04:29
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:40:51
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'supplement'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '1000'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'IU (IU)'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'UN UNK 2020'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	20 Oct 2020 16:35:17
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'UN Oct 2020' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 16:35:17
User entered empty.	Kaitlin Mason (b) (4)	20 Oct 2020 16:35:17
	(b) (4)	
	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User entered '1'	System	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User entered '1'	System	08 Sep 2020 18:41:08

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:19:54
User entered '804 (804)'	System	08 Sep 2020 18:41:08

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: LINUM USITATISSIMUM SEED, PRODUCTSYNONYM: FLAXSEED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 18:43:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:43:54
Data point term sent to Coder	System	08 Sep 2020 18:43:22
User entered 'Flax seed'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:42:26

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:28:50
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:05:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:05:18
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:40:58
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:42:26



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'supplement'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '1400'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2020'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:42:26
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:42:26

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:42:26

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:42:26



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 18:43:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:43:53
Data point term sent to Coder User entered 'Vitamin C'	System Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:43:22 08 Sep 2020 18:43:19

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:29:04
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:06:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:05:50
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:41:04
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:43:19

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'supplement'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '120'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2010'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:43:19
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:43:19



US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:43:19

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:43:19

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 06:25:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:25:37
Data point term sent to Coder	System	08 Sep 2020 18:47:35
User entered 'Probiotic for women'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:46:53

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:29:19
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:06:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 13:06:34
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:41:11
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	08 Sep 2020 18:46:53

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'supplement'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'capsule (CAPSULE)'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN UNK 2019'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	08 Sep 2020 18:46:53
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:46:53

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:46:53

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 18:46:53

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Dec 2020 20:51:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 20:51:23
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 21:09:44
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'standard for participant ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:00
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:42:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:05:53

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Sep 2020 15:05:53
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	30 Sep 2020 15:05:22
User entered 'IBUPROFEN'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'SEASONAL ALLERGIES'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '600'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '26 Aug 2020'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Sep 2020 15:05:02
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 15:05:02

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 15:05:02

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 15:05:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:01:11
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening - just a change in medication ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 14:16:03
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 SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:04:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: OXYMETAZOLINE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:06:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:06:48
Data point term sent to Coder	System	11 Nov 2020 18:07:19
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:52
User entered 'OXYMETAZOLINE HCL 0.05%' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:52

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: OXYMETAZOLINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 07:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 07:24:44
Data point term sent to Coder	System	30 Sep 2020 15:11:39
Data point term sent to Coder	System	30 Sep 2020 15:10:37
User entered 'oXYMETAZOLINE HCL'	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'SEASONAL ALLERGIES'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per DM CLR: Please note, 0.05 % is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 Drop (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 21:10:12
Query 'Per DM CLR: Please note, 0.05 % is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 Drop (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:57
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:52
User opened query 'Per DM CLR: Please note, 0.05 % is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 1 Drop (Other), etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:45:56
User entered '0.05'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'puff (PUFF)' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	18 Nov 2020 14:34:17
User entered 'Other (OTHER)'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query ' Per CDM: Dose Unit is recorded as 'Other - SPRAY', however, please confirm if Unit can be selected from already available option PUFF for SPRAY. If so please update as appropriate, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:11:27
Query ' Per CDM: Dose Unit is recorded as 'Other - SPRAY', however, please confirm if Unit can be selected from already available option PUFF for SPRAY. If so please update as appropriate, else clarify. Thank you.	Hassan Haji (b) (4) (b) (4)	18 Nov 2020 14:34:27
' answered with 'entered' (Site from DM).		
User entered empty; reason for change Data Entry Error	Hassan Haji (b) (4) (b) (4)	18 Nov 2020 14:34:17
User opened query ' Per CDM: Dose Unit is recorded as 'Other - SPRAY', however, please confirm if Unit can be selected from already available option PUFF for SPRAY. If so please update as appropriate, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:53:10
User entered 'spray' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Nov 2020 18:06:52
User entered '%'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
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	30 Sep 2020 15:11:20
User entered 'twice daily (BID)' reason for change: Data Entry Error	System	30 Sep 2020 15:11:20
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	30 Sep 2020 15:11:20
User entered empty.	(b) (4)	
	System	30 Sep 2020 15:10:02
	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 15:11:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:11:20
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Sep 2020 15:11:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 15:10:02
User entered empty.	System	30 Sep 2020 15:10:02
	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '31 Aug 2020'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '0'	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 16:13:36
User entered '2 Sep 2020'	(b) (4)	
	Sherry McCammon (b) (4)	30 Sep 2020 15:10:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 15:10:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User entered '2'	System	30 Sep 2020 15:11:20
User entered empty.	System	30 Sep 2020 15:10:02



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User entered '1'	System	30 Sep 2020 15:11:20
User entered empty.	System	30 Sep 2020 15:10:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:38
User entered '804 (804)'	System	30 Sep 2020 15:11:20
User entered empty.	System	30 Sep 2020 15:10:02

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:34:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:34:32
Data point term sent to Coder	System	23 Nov 2020 20:02:37
Coding entries removed.	Sherry McCammon (b) (4)	23 Nov 2020 20:02:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 20:14:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 20:14:09
Data point term sent to Coder	System	07 Oct 2020 19:32:51
User entered 'seasonal flu vaccine'	Hassan Haji (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'prophylaxis seasonal flu vaccine'	(b) (4)	
reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Nov 2020 20:02:10
User entered 'flu'	(b) (4)	
	Hassan Haji (b) (4)	07 Oct 2020 19:31:55
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '0.5' reason for change: New Information	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:14:01
User entered '1'	Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
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	08 Oct 2020 17:14:01
User entered 'mL (mL)' reason for change: New Information	(b) (4), (b) (6)	08 Oct 2020 17:14:01
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:31:55
User entered empty.	Hassan Haji (b) (4)	07 Oct 2020 19:31:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) Hassan Haji (b) (4)	07 Oct 2020 19:31:55



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
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	08 Oct 2020 13:19:50
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	08 Oct 2020 13:19:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	07 Oct 2020 19:31:55
	Hassan Haji (b) (4)	07 Oct 2020 19:31:55
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) Hassan Haji (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Nov 2020 20:02:10
User entered '3 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	07 Oct 2020 19:31:55
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '0'	Hassan Haji (b) (4)	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	Hassan Haji (b) (4)	07 Oct 2020 19:31:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Nov 2020 20:02:10
User entered '3 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	07 Oct 2020 19:31:55
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	07 Oct 2020 19:31:55

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User entered empty.	System	07 Oct 2020 19:31:55

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User entered empty.	System	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:12:29
User entered empty.	System	07 Oct 2020 19:31:55

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:37
Data point term sent to Coder Coding entries removed.	System Sherry McCammon (b) (4)	11 Nov 2020 20:18:53 11 Nov 2020 20:18:52
Coding entries removed.	(b) (4) Sherry McCammon (b) (4) (b) (4)	11 Nov 2020 20:18:52
User entered 'MELOXICAM' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	11 Nov 2020 20:18:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 14:14:29
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 Oct 2020 14:14:29
Data point term sent to Coder	System	15 Oct 2020 14:13:37
User entered 'vitamin D3'	Hassan Haji (b) (4) (b) (4)	15 Oct 2020 14:12:51

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
	(b) (4)	
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:29:45
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'Updated.' (Site from DM).	Toni Robinson (b) (4)	22 Oct 2020 13:08:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Toni Robinson (b) (4)	22 Oct 2020 13:07:56
	(b) (4)	
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:41:27
User entered 'No (N)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'HIP AND BACK PAIN' reason for change: Data Entry Error	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
	(b) (4)	
User entered 'supplement'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '15' reason for change: Data Entry Error	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
	(b) (4)	
User entered '2000'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
	(b) (4)	
User entered 'IU (IU)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	11 Nov 2020 20:18:52
	(b) (4)	
User entered 'UN Oct 2020'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	



**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	15 Oct 2020 14:12:51
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:18:52
User entered '1'	System	15 Oct 2020 14:12:51

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:18:52
User entered '1'	System	15 Oct 2020 14:12:51

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:18:52
User entered '804 (804)'	System	15 Oct 2020 14:12:51

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Nov 2020 20:21:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 20:21:36
Data point term sent to Coder	System	11 Nov 2020 20:20:55
User entered 'VITAMIN D3'	Sherry McCammon (b) (4) (b) (4)	11 Nov 2020 20:20:01

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:46:31
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 19:36:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Dec 2020 19:36:07
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 02:21:04
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	11 Nov 2020 20:20:01



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'SUPPLEMENT'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '2000'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'IU (IU)'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:28:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'UN Oct 2020'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:28:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	11 Nov 2020 20:20:01
	(b) (4)	

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 20:20:01

US3742022

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 20:20:01

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 20:20:01



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE, PRODUCTSYNONYM: DOXYCLINE [DOXYCYCLINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 15:35:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:35:05
Data point term sent to Coder	System	03 Dec 2020 17:20:52
User entered 'Doxycycline'	(b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Sinus Infection'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '100'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38



US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:28:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:28:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:09:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	15 Dec 2020 17:09:05
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:20:38

**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:28:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User entered '2'	System	03 Dec 2020 17:20:38



**US3742022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:28:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User entered '1'	System	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:28:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:18:16
User entered '804 (804)'	System	03 Dec 2020 17:20:38

US3742022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:28:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 20:55:45
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Feb 2021 15:56:24
	(b) (4)	

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered	System	10 Dec 2020 14:43:23
'USA-US127-2020-MRNA-1273-P301000013'		

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Karen'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Kotloff'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '685 W. Baltimore Street, HSF 480'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Baltimore'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '21201'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:05:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered 'US'	System	10 Dec 2020 14:43:59

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '3'	System	04 Jan 2021 19:16:51
User entered '2'	System	23 Dec 2020 21:05:35
User entered '1'	System	10 Dec 2020 14:43:59

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered	System	10 Dec 2020 14:43:23
'USA-US127-2020-MRNA-1273-P301000013'		

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Karen'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Kotloff'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '685 W. Baltimore Street, HSF 480'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Baltimore'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '21201'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:05:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered 'US'	System	10 Dec 2020 14:43:59



US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '3'	System	04 Jan 2021 19:16:51
User entered '2'	System	23 Dec 2020 21:05:35
User entered '1'	System	10 Dec 2020 14:43:59

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered '10/Dec/2020 14:43'	System	10 Dec 2020 14:43:59

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:28:13

**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 16:25:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:05:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 14:43:59

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered	System	10 Dec 2020 14:43:23
'USA-US127-2020-MRNA-1273-P301000013'		

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Karen'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Kotloff'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '685 W. Baltimore Street, HSF 480'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Baltimore'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '21201'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:05:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered 'US'	System	10 Dec 2020 14:43:59

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '3'	System	04 Jan 2021 19:16:51
User entered '2'	System	23 Dec 2020 21:05:35
User entered '1'	System	10 Dec 2020 14:43:59

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:17:27
User entered '23/Dec/2020 16:05'	System	23 Dec 2020 21:05:35

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:28:13

**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 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:17:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:16:54
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 21:05:35

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered	System	10 Dec 2020 14:43:23
'USA-US127-2020-MRNA-1273-P301000013'		

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'No (N)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Yes (Y)'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Karen'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Kotloff'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '685 W. Baltimore Street, HSF 480'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered 'Baltimore'	System	10 Dec 2020 14:43:23



**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:26:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:43:53
User entered '21201'	System	10 Dec 2020 14:43:23

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:05:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:26:43
User entered 'US'	System	10 Dec 2020 14:43:59

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
	(b) (4)	
User entered '3'	System	04 Jan 2021 19:16:51
User entered '2'	System	23 Dec 2020 21:05:35
User entered '1'	System	10 Dec 2020 14:43:59

**US3742022**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:28:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:17:27
User entered '04/Jan/2021 14:16'	System	04 Jan 2021 19:16:51

US3742022

Folder: SAE USA-US127-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:28:13

**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 16:25:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:17:27
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:16:54
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 19:16:51